BEFORE THE AMERICAN ARBITRATION ASSOCIATION
North American Court of Arbitration for Sport Panel

United States Anti-Doping Agency,	)	
	)	**RESPONDENT LANDIS' PRE-TRIAL BRIEF**
Claimant,	)	
v.	)	
Floyd Landis,	)	
	)	AAA No. 30 190 00847 06
Respondent.	)	

I.

INTRODUCTION

This case is about one thing only – whether the United States Anti-Doping Agency ("USADA") has proven to a comfortable satisfaction of the panel that Floyd Landis committed a doping violation during Stage 17 of the 2006 Tour de France ("Tour"). The comfortable satisfaction standard is a sliding scale that depends on the seriousness of the allegation being made. This inquiry thus begins with the seriousness of the allegation, which stands at the crossroads of the most prestigious professional bicycle race, an important juncture in anti-doping and a turning point in Mr. Landis' life and career. The Tour is the crown jewel of professional cycling. The Tour is one of the most watched sporting events on earth. Never before has a winner of the Tour been accused of

violating a doping offense during the Tour. Never before has the anti-doping system been subject to as much comment and review. The result of this inquiry means everything to Mr. Landis, whose reputation, livelihood and years of work to become Tour Champion are on the line. This inquiry thus demands a standard of proof very close to the "beyond a reasonable doubt" standard. USADA does not meet this high burden because it can not.

The analytic and procedural laboratory errors in this case violate the International Standard for Laboratories ("ISL"), applicable World Anti-Doping Agency ("WADA") Technical Documents, International Standards Organization ("ISO"), Standard Operating Procedures of LNDD and other standards of best practices. Taken individually, and in combination, they bar USADA from establishing that Mr. Landis committed any doping violation. They include:

- Violations of rules regarding chain of custody;
- Violations of rules regarding the preparation of laboratory documents;
- Violations of rules requiring more stringent procedures be used in GC-MS confirmation than GC-MS screening;
- Violations of rules preventing wrongfully identifying compounds in the GC-MS process;
- Violations of rules regarding running calibration controls and verifying calibration curves in GC-MS testing;
- Violations of rules regarding running tests on degraded urine samples;
- Violations of rules prohibiting matrix interference in chromatograms in the GC-MS testing;

- Violations of rules requiring the validation of positivity criteria for GC-C-IRMS testing;
- Procedures that create the absurd result that the alleged adverse analytic finding in the GC-C-IRMS testing would be positive at Labaratorie National de Depistage du Dopage ("LNDD") but not positive at many other WADA-accredited laboratories; and,
- Violations of other rules regarding linearity, maintenance and operation of testing equipment, stability and performance of testing.

It is critical to recognize that this wealth of errors presents a cohesive picture of a dysfunctional laboratory operating in a incompetent manner overall.[1] One or two errors, or even three or four errors may indicate the kinds of mistakes that are explainable. What makes this case deeply troubling is the breadth and scope of mistakes that render all of its laboratory results with respect to Mr. Landis' performance on Stage 17 utterly meaningless.

Adding to the weight of the laboratory errors, USADA's and LNDD's ultimate accusation – that Mr. Landis took testosterone during the Tour – makes no sense at all. Testosterone has no short term benefit, and Mr. Landis knew it. His performance on Stage 17 was the result of a carefully crafted strategy to win back the leadership of the Tour – at which point he knew he would be subject to doping tests. Mr. Landis' total

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[1] The exhibits in this case are organized as follows. Discovery pages provided to Mr. Landis that begin with the USADA, WADA, LNDD and AFLD bate-stamp numbers will be referred to by the prefix and number (for example, USADA0001 is referred to as Exhibit USADA0001). Additional documents and exhibits will begin with the prefix GDC followed by a number. This exhibit numbering sequence will remain consistent for the arbitration hearing.

testosterone level did not exceed the amount normal for Mr. Landis over many times he has been tested – his testosterone readings were completely normal. Mr. Landis' performance on Stage 17 was entirely within his athletic abilities – as shown by his historical training and power data. Lastly, and perhaps most in line with common sense, in order for Mr. Landis to have committed a doping offense with a drug that would not help him in an amount too small to matter, he would have violated the principles of honest hard work and sacrifice that put him in second place in the Union Cycliste International Rankings at the start of the 2006 Tour.

In response, USADA struggles to shove a square peg into a round hole by pointing to areas where LNDD actually did things properly. Many of these arguments, as will be shown, are simply not true. For example, USADA contends that Mr. Landis' adverse analytic findings would be positive by any criteria. *See* USADA's Pretrial Hearing Brief, at 58. Not true. UCLA's anti-doping laboratory, Australia's anti-doping laboratory and Cologne's anti-doping laboratory would not conclude Mr. Landis' confirmation carbon isotope ratio test was an adverse analytic finding. Others are unsupported by any authority. *See* id. at 32-48 (citing to evidence in violation of the Panel's procedural orders). Appropriate motions to strike will be filed. At other places, it has simply ignored where LNDD grossly erred – and fails to account for the holistic incompetence described above. *See* id. at 66 (attempting to justify, without basis, the rules prohibiting testing in the presence of degredation of sample). In doing so, USADA misses the mark – it has the burden of proving comfortable satisfaction to very high standard for LNDD's

results. Simply defending itself by pointing to alleged areas where LNDD performed work properly (or criticizing portions of Mr. Landis' brief designed to alert the panel of issues that justify additional discovery) simply do not, and should not suffice.[2]

Pursuant to the telephonic status conference of April 24, 2007, Mr. Landis will further supplement this brief upon the review of the Standard Operating Procedures and the data from the forthcoming electronic data files. Even without such supplementation, USADA has demonstrated that it has failed its burden of persuasion because it can not meet it. Mr. Landis won the 2006 Tour fair and square, as will be proven at the arbitral hearing.

II.

STATEMENT OF FACTS

A. FACTUAL OVERVIEW

Floyd Landis was born and raised in Farmersville, Pennsylvania and was raised as a Mennonite in an area that was, and still is, a predominately Mennonite community. Traditional Mennonite values of modesty, devotion to faith, honest hard work and selflessness were instilled in him and his five siblings. Mr. Landis first learned to ride a bicycle for simple transportation and recreation, but he soon displayed enormous natural talent. He won the first mountain bike race he entered, and in 1993, was crowned junior national champion. Soon afterwards, he stated that he would win the Tour de France one

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[2] Mr. Landis hereby incorporates his Discovery Brief by reference.

day. He continued to race from that time until his results attracted the attention of the United States Postal team, where he helped Lance Armstrong win three straight Tour de France victories, from 2002 to 2004. His native talent for climbing mountains – a pure indicator of strength and power – led the Phonak team to sign him as a leader in January 2006.

By July 2006, Mr. Landis was experiencing the best season of his career, each race showing a steady progression of skill and strength, built upon the athletic prowess built while with United States Postal team and team Discovery. By the time he lined up to start the 2006 Tour de France ("Tour"), he had already won the 2006 Amgen Tour of California, the 2006 Paris-Nice and the 2006 Tour de Georgia. He stood in second place in the UCI ProTour standings.

On July 23, 2006, Mr. Landis finished the 20th stage of the 2006 Tour de France as the yellow jersey holder[3] and leader of the General Classification by 57 seconds. During the Tour, Mr. Landis provided urine samples to the UCI on the following dates: July 4, 11, 13, 14, 18, 20, 22 and 23, 2006.[4] *See* Exhibits USADA 0412, 0419, 0426, 0433, 0440, 0447, 0458, 0465. All of the urine samples provided by Mr. Landis during this period were tested at LNDD. *See* Exhibits USADA 415, 422, 429, 436, 443, 451, 461, and 468. On July 25, 2006, LNDD notified CPLD and the UCI that its test of the A

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[3] The yellow jersey is given to the cyclist in first place in the general classification.

[4] Mr. Landis provided blood samples on July 11 and 19, none of which are at issue here.

Sample from the specimen taken from Mr. Landis on July 20 ("Stage 17 Sample") displayed an Adverse Analytic Finding ("AAF"). *See* Exhibits USADA 188, 199.

On July 27, 2006, USADA notified Mr. Landis of the AAF and assumed prosecution of this matter. *See* Exhibits GDC0001-0003. In its communication to Mr. Landis, USADA indicated that he could either request the testing of the B Sample or simply accept the AAF from the A Sample of the Stage 17 Sample. Mr. Landis refused to accept the AAF from the A Sample and elected to have the B Sample tested. *See* Exhibits GDC0004-0005. Between August 3 and 5, 2006, LNDD conducted its testing of the B Sample from the Stage 17 specimen. *See* Exhibits USADA 0365, 0366. LNDD eventually concluded that the B Sample confirmed the AAF, using its Gas Chromotography/Combustion/Isotope Ratio Mass Spectrometry ("GC/C/IRMS" or simply "IRMS") instrument. *See* Exhibits 0365, 0366. On August 5, 2006, LNDD notified Mr. Landis, USADA, the AFLD, the UCI and the media of its findings. *See* Exhibit GDC0006. On September 11, 2006, Mr. Landis filed pleadings before USADA's Anti-Doping Review board in order to have this case dismissed. *See* Exhibits GDC0007-0022. On September 18, 2006, the Anti-Doping Review board rejected Mr. Landis' petition, and the instant litigation began. *See* Exhibit GDC0023.

B. STAGE 17 SAMPLE TESTING CHRONOLOGY

USADA's Brief contains a detailed description concerning the collection and transportation of the Stage 17 Sample, with specific detail on the collection and transportation of Mr. Landis' sample to LNDD. Noticeably absent from its brief,

however, is a correspondingly detailed description of the chronology of the Stage 17 A and B samples once they arrived at LNDD.

1. July 20, 2006

Mr. Landis' Stage 17 A and B samples was received by LNDD at 21:35. *See* Exhibits 22 and 24. According to LNDD records, at 22:15 the A bottle was placed in the refrigerator and the B bottle was placed in the freezer. *See* Exhibit USADA0253.

2. July 21, 2006

At 7:35, L. Martin ("Martin") removed the A bottle from the refrigerator. At 8:10, Martin prepared the aliquot for the EPO test. *See* Exhibit USADA0253. Between 8:10 and 9:10, LNDD has no documentation concerning the intra-laboratory transfer of the A bottle that occurred between Martin and Garcia. At 9:10, Garcia prepared an aliquot for the T/E test. *See* Exhibit USADA0253. At 9:25, the A bottle was placed in the refrigerator. *See* Exhibit USADA0253. At 9:40, the T/E aliquot was sent to a chemistry laboratory. *See* Exhibit USADA0255. The T/E chemistry workup, described later, lasted from 9:40 to 14:45. *See* Exhibits USADA0037-0039, 0043. The T/E or GC/MS test (described below) was preformed at 19:36 by Galatola, and was monitored by Cerpolini. Exhibit USADA0255. At an unknown time, Cerpolini read the T/E data. Exhibit 0054.

3. July 22, 2006

At 9:25, Cerpolini removed the A bottle from the refrigerator. Exhibit USADA0253. At 10:50, Cerpolini created the first confirmation T/E aliquot. Exhibit USADA 0253. At 11:02, the first confirmation aliquot was sent to chemistry. Exhibit USADA0200. The first T/E aliquot was at chemistry from 11:02 to 16:00; the chemistry

was performed by Cerpolini. Exhibit USADA0200. At 11:20, Mongongu prepared a GC-C-IRMS (described below) aliquot using the A bottle. Once again, LNDD has no documentation concerning the intra-laboratory transfer of the A bottle between Cerpolini and Mongongu that occurred between 10:50 to 11:20. At 11:25, the IRMS aliquot is taken to the chemistry laboratory by Mongongu. Exhibits 119-120. The IRMS aliquot was at chemistry from 11:25 to 19:40, which is performed by Mongongu. Exhibits USADA0119-0120. At 12:40, Cerpolini places the much traveled A bottle in the refrigerator. Exhibit USADA0253. At 18:02, the first A confirmation T/E test is conducted. Exhibits USADA0201-0205.

4. July 23, 2006

From 9:05 to 14:25, the IRMS aliquot was in chemistry, which was performed by Mongongu. Exhibits USADA0120-0121. At 14:30, the A bottle was removed from the refrigerator by Cariou, and at 15:00 the second A confirmation T/E aliquot is made by Cariou. Exhibits USADA0253, 0256. Yet again, LNDD has no documentation concerning the location or handler of the A bottle from 15:00 to 17:00. From 15:10 to 17:25 the second confirmation T/E aliquot is in chemistry, which was performed by Cariou. Exhibit USADA0079. At 17:00, while Cariou performed the chemistry on the second T/E aliquot, Cariou returned the A bottle to the refrigerator. Exhibit USADA0253. At 21:23 Mongongu read the data from the IRMS test. Exhibits USADA0155, 0185-0186.

5. **July 24, 2006**

Sometime before 8:20, Cerpolini removed the A bottle from the refrigerator. Exhibit USADA0253. At 8:20, Cerpolini placed the A bottle in the freezer. Exhibit USADA0253. From 9:10 to 10:54, chemistry continued on the second T/E confirmation test by Cariou. Exhibit USADA0079. Sometime after 12:54, Cerpolini read the data from the first confirmation T/E test. Exhibits USADA0212-0215, 0223. At 13:28, the second T/E confirmation test was conducted. Exhibit USADA0256, 0080-0084. At 17:15, the second confirmation data was read by Cerpolini. Exhibits USADA0092-0093, 0101.

6. **July 25, 2006**

At a time unknown based on the documentation, Buissiou re-conducted either the first or second A T/E confirmation aliquot using the screen method. Exhibits USADA 0057-0059.

7. **July 28, 2006**

There is no documentation concerning when the B bottle was removed from freezer 3, by whom the bottle was removed, and where the bottle was located after it was removed. At 15:45, the unknown operator replaced the B bottle in freezer 5. Exhibit USADA 0254.

8. **August 3, 2006**

At 9:12, the B bottle was removed from the freezer by Cerpolini. Exhibit USADA0251. At 11:03, Frelat creates the B IRMS aliquot. Exhibit USADA0254. LNDD has no documentation concerning the intra-laboratory transfer of the B bottle from

Cerpolini to Frelat which occurred sometime between 9:12 and 11:03. At 11:05, Barlagne creates an aliquot for the B T/E test. Exhibit USADA0254. LNDD has no documentation concerning the intra-laboratory transfer of the B bottle between Frelat and Barlagne. From 11:26 to 18:05, the B IRMS aliquot is in chemistry, which is performed by Frelat. Exhibits USADA0299-0300, 0106-0109. From 11:45 to 16:25, the B T/E aliquot is at chemistry, which is performed by Barlagne. Exhibits USADA0264, 0074-0076. At 19:45, the B T/E test is conducted. Exhibits USADA0256, 0265-0268, 0272.

9. August 4, 2006

At 7:39, the B T/E test data was read by Barlagne and Cerpolini. Exhibits USADA0269-0271, 0277-0284, 0288. Frelat continued to perform chemistry on the B IRMS aliquot from 9:16 to 16:40. At 17:00 Frelat conducted the IRMS test. Exhibit USADA0302. At a time unknown, Frelat read the IRMS data. Exhibits USADA0351-0352.

III.

TESTOSTERONE DID NOT AID MR. LANDIS

IV.DURING STAGE 17

A. TESTOSTERONE

1. Testosterone Generally

Testosterone is a steroid hormone within the human body naturally occurring in both men and women. In men, testosterone is produced by Leydig cells, and primarily secreted by the testes. Exhibits GDC0034-0053. Testosterone performs many critical functions in the adult male, including enhancing libido, energy and the maintainence of

bone and muscle mass and secondary sexual characteristics Testosterone is derived from cholesterol through a series of enzyme-regulated steps. *See* J. Kraemer and A. D. Rogol, The Endocrine System in Sports and Exercise, at 526-28. After synthesis, testosterone is secreted into the blood stream.

The effects of testosterone after being secreted in the blood are complicated. *See id.*

2. Short-Term Testosterone Use Has No Effect On A Cyclist's Performance

Acute or short-term administration of testosterone has no known effect on athletic performance. Dr. Gary Wadler, a member of the World Anti-Doping Agency, and a member of that organization's "prohibited lists and methods" committee, as well as a spokesman for the American College of Sports Medicine opined in an interview that LNDD's Stage 17 results do not "add up." See Exhibits GDC0054-0055; GDC0056-0061. According to Wadler, one-time use of steroids could result in an abnormal test, but would have had *no effect on performance* and could not account for Landis' win of the Tour or of Stage 17 of the Tour:

> Steroids can increase strength and improve recovery time and prevent the breakdown of muscle, maybe make him more assertive and aggressive. All of those could have some positive attribute. **But most steroids are given in cycles [6-12 weeks]** and in context of working out in a gym with weights. **It makes no sense to me why an athlete would take testosterone the day of a race when it doesn't work that way. It doesn't make sense in terms of the pharmacology of the drug, and it really doesn't have the attributes that would be attractive to a cyclist** -- particularly one running the risk of violating anti-doping regulations.

The performance-enhancing effects of testosterone are erroneously assumed to be well-established; however, such effects are, in fact, controversial in populations of normal men. *See* Exhibits GDC0062-0063. In 1996, a study found that the common perceptions that testosterone promotes endurance was found to be unsubstantiated. See Exhibits GDC0272-0278. More recent reviews reiterate this point: testosterone's effects, if any, are most likely to be observed in populations of highly trained athletes performing *strength* tasks like weightlifting, not *endurance* tasks like cycling, and only then after supraphysiologic doses over a period of weeks. Exhibits GDC0249-0271.

Further, there is significant literature that in addition to testosterone being a dose-dependent steroid, there is a *threshold* amount that must be administered in order to observe any effect at all. Indeed, a study published in 2001 found that 50 mg of testosterone, thought at the time to be double the natural replacement level, administered over a 20 week period did not result in any meaningful effect. See Exhibit GDC0279-0288. A 2004 study found that the conclusions in the 2001 study had not be contradicted by any later study.

Although there is literature that supports the contention that testosterone can increase lean muscle mass, there has been no study that has found these effects with less than six weeks of high dose testosterone administration. Notably, no increases in either body weight or lean muscle mass was seen where testosterone was only taken for *three* weeks. Also, even with prolonged administration, there is no guarantee to see meaningful effects. One study failed to note an increase in muscle circumference even after administration of testosterone and other steroids over a *twenty-four week period.*

Most importantly, the 2004 study again concluded that there was no evidence to support the contention that testosterone use has any impact on endurance and recovery.

3. Floyd Landis' Testosterone Was Normal

USADA attempts to demonstrate that Mr. Landis longitudinal GC/MS values show a doping violations. *See* USADA Pre-Hearing Brief, at 125. Without conceding the validity of this flawed study, all it really shows is that Mr. Landis' testosterone on Stage 17 was very similar to his testosterone levels on other stages.

B. STAGE 17 WAS NOT A SUPERHUMAN PERFORMANCE FOR FLOYD LANDIS

During and after the 2006 Tour, commentators opined that Mr. Landis' performance on Stage 17 would not have been possible but for the use of a performance-enhancing drug. Aside from the fact a single use of testosterone is not performance enhancing and, contrary to those allegations, Mr. Landis' performance during Stage 17 was not at all unusual for Mr. Landis. Not only did he enjoy spectacular success through 2005 and the first half of 2006, Mr. Landis rode many of those events in 2005 and 2006 with a power meter. The data from that power meter demonstrates that from a statistical perspective, his performance on Stage 17 was entirely consistent with his past achievements.

1. How's Power Measured?

Beginning in 2003, in training and in competition, Mr. Landis used a device called the "PowerTap." The PowerTap device replaces the rear hub and axle of the bicycle, and measures the amount of power generated by the cyclist as expressed in watts. The data

from the PowerTap is sent wirelessly from the rear hub to an output device mounted on the handlebars. After the rider has completed his or her training or race, the data on the output device can easily be downloaded onto a computer for analysis.

2. What Does Power Data Mean to a Cyclist

Power data is an important consideration in training and competition because power is a function of how hard and fast a cyclist pedals. Further, power data is an objective measure of exercise intensity and a direct determinant of physical performance. Once the information from the PowerTap device is downloaded, several metrics can be analyzed. These metrics include intensity,[5] total energy expended,[6] distribution of intensity,[7] and peak power output for any given segment of time.[8]

Mr. Landis used the PowerTap device during Stage 17 and the following data was measured: Intensity was 281 watts; Total Energy Expended was 5,456 kilojoules; Time at lactate threshold[9] was 162 minutes; Time above lactate threshold was 43 minutes; Five

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[5] Intensity is the average power used during the ride measured in Watts.

[6] Total energy expended is synonymous with the amount of work performed by the cyclist, and is measured in Kilojoules.

[7] The amount of time spent below, at, and above the lactate threshold.

[8] The highest power measurement for either a 5, 10, or 30 minute period.

[9] Lactate is a by-product of anaerobic metabolism. During light and moderate-intensity exercise, the blood concentration of lactate remains low, and the body is able to absorb lactate faster than the muscle cells are producing it. However, as exercise intensity increases, there comes a point at which lactate removal fails to keep up with the rate of lactate production. This point is referred to as the lactate threshold (LT). Excessive blood lactate and hydrogen ion concentrations combine to interfere with

[Footnote continued on next page]

Minute Peak Power was 451 watts; Ten Minute Peak Power was 431 watts; and Thirty Minute Peak Power was 401 watts. This power data from Stage 17 appears as follows:

Metric	Data
Intensity	281 watts
Total Energy Expended	5,456 Kilojoules
Time at Lactate Threshold	162 Minutes
Time above Lactate Threshold	43 Minutes
Five Minute Peak Power	451 Watts
Ten Minute Peak Power	431 Watts
Thirty Minute Peak Power	401 Watts

3. Stage 17 Power Data Is Similar To Mr. Landis' Previous Data

Although Mr. Landis' performance, from a power perspective, was superb during Stage 17, it was not his best performance, much less a performance that he had not

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[Footnote continued from previous page]

efficient and proper muscle contraction, and as a result, power output drops, suffering increases and you are forced to slow down.

previously duplicated or bettered in training and racing. Indeed, for each individual metric, there are several previous races in which Mr. Landis exceeded the data from Stage 17.

Mr. Landis began using the PowerTap device in 2003. Mr. Landis, and his coaches, however, did not download the data from the device onto a computer. It was not until 2005, after Mr. Landis left Team Discovery and hired a specific power coach, that Mr. Landis' power data was downloaded from the PowerTap device into the computer. There are eighty-one other data points from various races in 2005 and 2006 that can be compared to the Stage 17 data.

Comparing these data points to the data from Stage 17, it is evident that there is nothing remarkable about the power exerted by Mr. Landis during Stage 17. Out of the eighty-one data points Mr. Landis had an average intensity of more than 281 watts in six rides. In other words, seven percent of Mr. Landis' rides were more intense than Stage 17. Further, Mr. Landis exerted more total energy than he did during Stage 17 on eight other rides. That means that in ten percent of Mr. Landis' rides in 2005 and 2006, Mr. Landis exerted more total energy than he did during Stage 17.

Comparing the peak power output for any given segment measurements follow a similar pattern. Mr. Landis has eleven rides, or fifteen percent, in which his five minute peak power output is greater than during Stage 17. And, Mr. Landis has six rides, or seven percent, in which his ten minute peak power is greater than during Stage 17.

The most telling comparison between Mr. Landis' pervious power data and Stage 17 is the distribution of intensity. Mr. Landis has ten rides, or fourteen percent, in which

the amount of time at lactate threshold was greater than in Stage 17. And, most critically, in 20 other rides, Mr. Landis spent more time above his lactate threshold level than in Stage 17. Indeed, in twenty-nine of Mr. Landis' other recorded rides, he spent more time above his lactate threshold level.

Accordingly these comparisons establish that Mr. Landis' performance during Stage 17 was not superhuman.

C. PURE POWER DOES NOT WIN RACES

In non-timed events and steep climbs, there is a strong disassociation between power output and race placing. In these types of races, overall race tactics play a vital role. For instance, the protected team captain expends the least amount of energy but places the highest at the end of the day.

This is further exemplified by comparing the power data and race finish between Mr. Landis and another rider, Will Frischkorn, during the Brasstown Bald Stage of the Tour of Georgia. Mr. Frischkorn's power data was far superior to Floyd's; Mr. Frischkorn's intensity, total energy exerted and distribution of intensity exceeded Mr. Landis. Power, however, does not win races; Mr. Frischkorn ended the stage in 79th place, whereas Mr. Landis finished second.

	Moving		Pedaling		Work	Time (Min) Distributed Between a W/Kg:		
	Watts	W/Kg	Watts	W/Kg	Kjoules	> 4	4 to 6	> 6
Floyd (2nd)	**272**	**3.90**	**318**	**4.56**	**4,104**	**117**	**88**	**39**
Will (79th)	**292**	**4.23**	**322**	**4.66**	**4,618**	**96**	**126**	**42**

1. **Mr. Landis' Stage 17 Win Was The Result of Superior Race Tactics and Strategy**

Mr. Landis, and his coaching staff, devised a specific strategy to succeed on Stage 17. This strategy was designed not simply to win Stage 17, but to put him back into contention to win the Tour. Essentially, Mr. Landis decided to challenge the peloton on the first climb and see if they would chase. Mr. Landis assumed that the three leaders would not chase him because they would think that he could not sustain the pace throughout the Stage without his team's support. By breaking out early, Mr. Landis created a "civil war" among the leaders because none of them wanted to expend his team's resources to catch him. Moreover, Mr. Landis knew that if he paced himself at 360 to 390 watts on the climbs, he would be able to sustain the lead during the Stage.

Additionally, since Mr. Landis had broken away from the peloton, he was able to have his support vehicle ride next to him during most of the stage. By having his support vehicle in such close range, Mr. Landis received seventy bottles of water, three to four times more than the cyclists in the peloton. In addition to the hydration effects, Stage 17 was a warm day and Mr. Landis kept his body cool by dosing it with ice cold water.

Accordingly, Mr. Landis' performance on Stage 17 was well within Mr. Landis' other performances and his success during the Stage was a direct result of superior strategy and tactics.

V.

ARGUMENT

A. USADA'S BURDEN OF PROOF

The standard of proof in an anti-doping case is a multi-step process with a shifting burden. The steps are as follows:

First, the Anti-Doping Organization, in this case USADA, "shall have the burden of establishing than an anti-doping rule violation has occurred." *See* UCI Cycling Regulations, Art. 16, exhibits GDC0070, *see also* the World Anti-Doping Code, Art. 3.1, exhibit WADA0453-0496 (The language in both the WADA Code and Art 16 are identical except for the substitution of "UCI and its National Federations" for "Anti-Doping Organizations). In this case, USADA seeks to establish its burden by the alleged adverse analytic findings of both the GC-MS tests and the GC-IRMS tests from Stage 17 of the 2006 Tour. Once USADA introduces evidence of an adverse analytic finding, the results are presumed correct because "WADA-accredited laboratories . . . are presumed to have conducted *Sample Analysis* and custodial procedures in accordance with the *International Standard* for laboratory analysis." *See* UCI Art. 18, exhibit GDC0071.[10]

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[10] USADA asserts – without any authority at all – that this presumption is "supported by the fact that one of WADA's core responsibilities is to monitor the labs . . . " Because it is unsupported by any citation or logic, USADA's editorial should be ignored.

Second, Mr. Landis is entitled to rebut this presumption by establishing that a departure from the International Standard occurred. *See* UCI Art. 18, exhibit GDC0071 ("The Rider may rebut this presumption by establishing that a departure . . . occurred"), *see also* WADA Code Art. 3.2.1, exhibit GDC0453-0496. The standard of proof by which Mr. Landis must meet this standard is by a "balance of probability." *See* id. ("the burden of proof upon the Athlete . . .shall be by a balance of probability").

Third, once that presumption is rebutted by a showing of such a departure, then USADA shall "have the burden to establish that such departure did not cause the Adverse Analytical Finding. . . ." WADA Code Art. 3.2.1, exhibit GDC0453-0496.

In establishing its burden, the applicable rules require that USADA must present evidence of a doping violation to the "comfortable satisfaction of the hearing body bearing in mind the seriousness of the allegation which is made." *See* UCI Anti-Doping Regulations, Article 16, exhibit GDC0070, and Article 3.1 of the World Anti-Doping Code, exhibit GDC0453-0496. The Court for Arbitration of Sport in USADA v. Montgomery (CAS 2004/O/645), at pp. 13-14, exhibit GDC0148-0149, has defined the "comfortable satisfaction" burden as a sliding scale of probability depending on the seriousness of the allegation. The Court for Arbitration of Sport explicitly stated that:

> In all cases the degree of probability must be commensurate with and proportionate to those allegations; the more serious the allegation the higher the degree of probability, or 'comfort', required.

Id. (emphasis added). Thus, accordingly, in light of the UCI and WADA rules, and the case law, when the allegation of doping is minor, the anti-doping organization must present evidence that establishes that, more likely than not, the doping violation occurred.

When the allegation of doping is serious, however, an even greater probability of the violation must be shown. The rationale for this heightened burden is that "the more serious the allegation the less likely it is that the alleged event occurred and, hence, the stronger the evidence required before the occurrence of the event is demonstrated to be more probable than not. . . . The gravity of the allegations and the related probability or improbability of their occurrence become in effect part and parcel of the circumstances which must be weighed in deciding whether, on balance, they are true." *Id.*

In this case, given the seriousness of the allegations, USADA must be held to the most stringent burden permitted by the rules. The factors supporting the seriousness and gravity of the allegations are as follows:

1. the allegations involve the crown jewel of professional cycling, the Tour de France;
2. the allegations involve a sporting event that attracts world-wide attention and participation;
3. the allegations involve not just a participant in the Tour de France, but the winner of the Tour;
4. this case involves the first time in history that the winner of the Tour de France has been charged with a doping offense arising during the Tour;
5. the allegations involve the career, livelihood and reputation of Mr. Landis;
6. the allegations have very substantial financial impact on Mr. Landis;

7. the allegations against Mr. Landis have been accompanied by a media campaign in France, along with attendant leaks of that information, *see* GDC0324-0332, that have attacked Mr. Landis' reputation; and,
8. the allegations have attracted international attention to the role and fairness of the anti-doping protocol.

To establish the alleged doping violation here, given the seriousness of the allegations, USADA should be held to the most stringent burden permitted by the rules. No other case brought in the anti-doping case has had this many potential ramifications for the athlete or for the anti-doping system. Pursuant to the rules, this burden must be as close to "proof beyond a reasonable doubt" as possible. *See* Montgomery, supra, at ¶13, exhibit GDC0148 ["From this perspective, and in view of the nature and gravity of the allegations at issue in these proceedings, there is no practical distinction between the standards of proof advocated by USADA [comfortable satisfaction] and the Respondents [beyond a reasonable doubt]."]

Thus, although USADA is entitled to an initial presumption, once rebutted by Mr. Landis showing **any** deviation from **any** ISL standard, USADA must satisfy its burden to a comfortable satisfaction, **which in this case is akin to that of beyond a reasonable doubt**, that the deviation **did not** cause the Adverse Analytical Finding or that the deviation **did not** change the result. This burden is not easily satisfied.

In this case, as Mr. Landis will show that there were numerous such deviations, none of which USADA has been able to demonstrate by any standard did not cause the alleged adverse analytic findings in this case. Indeed, as stated by the panel in UCI v.

Landaluce, "[i]t is virtually impossible to prove a negative fact." CAS 2006/A/1119, p. 23, at ¶111, exhibit GDC0189 (translated GDC0215).

B. HOW MANY WAYS CAN LNDD BOTCH AN ANTI-DOPING TEST?

The testing for testosterone is a complex procedure that does not rely upon simply identifying the presence of testosterone in urine, but rather the nature of the testosterone in urine. *See* Ayotte, C., et al., GC/C/IRMS and GC/MS in "Natural Steroid Testing, RADA(9) (2001) ("Testing for the administration of natural steroids is a complex task requiring the identification and quantification of a number of parameters of the steroid profiles . . . .") *See* Exhibit GDC0024-0029. LNDD uses two different tests to determine whether a particular sample shows evidence of testosterone doping. These two tests are the Testosterone/Epitestosterone Test ("T/E test or GC/MS test) and the GC-C-IRMS ("IRMS") test. The T/E test is conducted first, and only if the T/E test is considered positive, will the IRMS test be conducted. LNDD, however, failed to conduct these test as required by the WADA rules. Given the totality of the errors and WADA rule violations committed by LNDD, USADA can not satisfy its significant ultimate burden that these blatant deviations and failures did not, even in the slightest fashion, affect its test results.

1. The Chain Of Custody Is Fatally Flawed

Before Mr. Landis' addresses LNDD's failures in the administration of the T/E and CIR testing, this panel should dismiss the anti-doping violation against Mr. Landis because LNDD significantly deviated from the WADA rules concerning chain of custody.

a. Usada Can Not Establish Complete Chain Of Custody Beyond A Shadow Of A Doubt

There are egregious and systematic breaks in the chain of custody in the handling of Sample 995474 in both the A and B sample bottles while at LNDD that significantly undercuts the reliability of the LNDD's findings. Having an impeccable chain of custody is necessary "[t]o ensure that the urine tested suffered no contamination, tampering, or mislabeling." Catlin, Cowan, Donike et al., "Testing Urine for Drugs," International Federation of Clinical Chemistry (1992), Exhibit GDC0219-0232. Indeed, pristine chain of custody is of such vital importance that WADA ISL 5.2.2.2, exhibit WADA 0079-0135, requires (1) that each laboratory have internal chain of custody procedures to maintain control of and account for the samples while in the laboratory and (2) that the procedures must incorporate Technical Document 2003LCOC. Exhibit GDC0233. Technical Document 2003LCOC requires, in part, the following:

1. That the laboratory must have documentation establishing a "*continuous* record of individuals in possession of the samples . . . ." (emphasis added); and
2. That the laboratory must record that the sample has been placed in a control area whenever the sample is not in possession of a laboratory operator. Id.

Significantly, the chain of custody must document all intra-laboratory transfers. Catlin, Cowan, Donike et al., "Testing Urine for Drugs," International Federation of Clinical Chemistry (1992), Exhibit GDC0219-0232.

USADA has failed to provide Mr. Landis with any SOP concerning LNDD's chain of custody procedures. Given that no document containing LNDD's chain of custody procedure was produced, no such chain of custody document can be used during the hearing. Procedural Order # 2. Accordingly, LNDD is in direct violation of Technical Document 2003LCOC.

Further, USADA has failed to provide the original contemporaneous documents that would support the chain of custody summary report provided in discovery. Without those documents, the summary page is not sufficient to establish an "impeccable" chain of custody. Indeed, USADA admitted in its Pre-Hearing Brief that Exhibit USADA0257, a similar chain of custody summary report regarding aliquots, is not the original chain of custody document and was prepared only to assist the reader. *See* USADA Pre-Hearing Brief at Exhibit 32A. In addition to admitting that this, and the other summary chain of custody reports, were not contemporaneous chain of custody documents, USADA admits, after it was pointed out by Mr. Landis in his discovery motion, that the summary report contained several errors. Without the underlying supporting documentation, USADA's chain of custody summary report, Exhibits USADA0253 and 0254, should be disregarded as there is no method to determine its accuracy.

Even if USADA's non-contemporaneous summary report is considered, LNDD systematically failed to record intra-laboratory transfers of the "A" and "B" sample bottles.

1. On July 21, 2006, LNDD failed to record who removed the "A" sample from the refrigerator and when he or she did so. Exhibit USADA0253.

2. On July 21, 2006, LNDD failed to record how the "A" sample bottle was transferred from Martin in Salle 107 to Garcia in Salle 106, when the sample was transferred, and where it was transferred. Exhibit USADA0253.

3. On July 22, 2006, LNDD failed to record who removed that "A" bottle from the refrigerator and when it was removed. Exhibit USADA0253.

4. On July 22, 2006, LNDD failed to record how the "A" sample bottle was transferred from Cerpolini in S. 103 to Mongongu in S. 104, which occurred sometime between 10:50 to 11:20, where it was transferred, and when it was transferred. Exhibit USADA0253.

5. On July 22, 2006, LNDD failed to record how the "A" sample bottle was transferred from Mongongu in S. 104 to Cerpolini which occurred sometime between 11:20 and 12:45, where the transfer occurred, and when it was transferred. Exhibit USADA0253.

6. On July 23, 2006, LNDD failed to record who removed the "A" sample bottle from the refrigerator, and when the transfer occurred. Exhibit USADA0253.

These egregious and systematic errors occurred in the handling of the "B" sample as well. Indeed, the B sample chain of custody is even more questionable.

1. On July 28, 2006, LNDD failed to record who removed the "B" sample bottle from the freezer, and where this transfer occurred. Exhibit USADA0254.

2. On August 3, 2006, LNDD failed to record how, where, and when the "B" sample was removed from the freezer. And, LNDD failed to record the transfers of how, when, and where the B sample bottle was transferred from Cerpolini in an unknown location to Frelat in S004, which occurred somewhere between 9:12 and 11:03. Exhibit USADA0254.

3. On August 3, 2006, LNDD failed to record the transfer of the "B" sample bottle from Frelat in S004 to Barlagne in S103. Exhibit USADA0254.

The severity of LNDD's systematic failure to record intra-laboratory transfers is apparent when compared to the method of documenting intra-laboratory transfers at the UCLA and Montréal laboratories. Exhibit GDC0030-0031 is a chain of custody document from the Montreal laboratory. This chain of custody document establishes the time, date, person, or place, who had the sample bottle, and the person, or place, who the sample bottle was given. This is in direct contrast to LNDD, which simply records only one-half of the intra-laboratory transfer, i.e., the person who received the sample bottle and not the person who provided the bottle.

LNDD's chain of custody documents are in stark contrast to UCLA's chain of custody documents as well. Exhibit GDC0032-0033, contains two chain of custody documents from the UCLA laboratory. Similar to the Montréal laboratory, UCLA records both parties to the intra-laboratory transfer, which, unlike LNDD, creates a continuous chain of custody.

In addition to the systematic failure to record both parties to the intra-laboratory transfers, LNDD's overall handling of the sample bottles in this case is dubious:

1. On July 21, 2006, the "A" sample bottle was removed from the refrigerator at 7:25 and was not returned until 9:25, two hours later. In fact, during those two hours, the only documented task completed was the creation of aliquots. See Exhibit USADA0253.

2. On July 22, 2006, the "A" sample bottle was removed from storage at 9:05 and not returned until 12:45, over three and a half hours later. During these three and a half hours that the "A" sample bottle was removed from storage, the operators who purportedly had possession of the "A" bottle were conducting chemistry for both the T/E and IRMS tests. See Exhibits USADA0119-0120, 0200.

3. On July 23, 2006, the "A" sample bottle was removed from the refrigerator at 14:20 and not returned until 17:00, over 2 and half hours later. During this time, the aliquot for the second confirmation T/E test, which was the only reason for removing the bottle from storage, was completed at 15:00; yet, the bottle was not replaced

until two hours later. See Exhibits USADA0079, 0253, 0256. There is no explanation for why the bottle was needlessly sitting around the laboratory.

Breaks in the chain of custody are fatal to the reliability of LNDD's test results. In fact, in a 1994 report to the International Amateur Athletic Federation regarding laboratory procedures, Prof. Manfred Donike stated that "[t]he chain of custody . . . must be impeccable before a positive finding can lead to sanctions." This documentation can hardly be characterized as an impeccable chain of custody. In addition to being less than impeccable, LNDD's systematic failure to include intra-laboratory transfers is in direct violation of the WADA regulation and WADA Technical Document 2003LCOC concerning chain of custody.

These "breaks" in the chain of custody, or complete failure to record the chain of custody, constitute a fatal flaw in the testing process that cannot be overcome by USADA. The breaks in the chain of custody, as illustrated above, obviate the need to even examine the laboratory results, as an impeccable chain of custody is necessary "[t]o ensure that the urine tested suffered no contamination, tampering, or mislabeling." Catlin, Cowan, Donike et al., "Testing Urine for Drugs," International Federation of Clinical Chemistry (1992), Exhibit GDC0219-0232. Accordingly, this Panel should find that USADA has not satisfied its burden of establishing a doping violation.

Furthermore, these errors did not occur in a vacuum. As will be discussed later in this brief, given the totality of the errors that LNDD committed while testing Mr. Landis' Stage 17 sample, USADA cannot establish, by the stringent burden they must overcome,

that Mr. Landis committed an anti-doping violation. Here, it is impossible for USADA to establish by a "comfortable satisfaction," given the blatant errors in the chain of custody in conjunction with LNDD's other blunders, that these errors did not affect Mr. Landis' test results.

2. LNDD's GC/MS Testosterone/Epitestosterone Ratio Test: A Case Study In Incompetence

a. The Theory of the GC/MS Test

The initial test performed by LNDD for testosterone is the Testosterone to Epitestosterone ratio test ("T/E test or GC/MS test"). The theory behind the T/E test is that the urinary testosterone to epitestosterone ratio remains relatively constant and is not known to be altered by exercise. Exhibit GDC0234. The administration of exogenous testosterone results in an increase in the concentration of testosterone in the urine; whereas, the epitestosterone levels remain unchanged. Id. Thus, the testosterone to epitestosterone ratio increases. Although it was originally believed the ratio of testosterone to epitestosterone in urine in adult males should be approximately 1:1. In fact, however, ratios as high as 15:1 or higher could be normal; conversely, some individuals naturally have low urinary T/E ratios that do not change even with the administration of exogenous testosterone. *See* exhibit GDC0235-0246.[11]

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[11] To increase the accuracy of the T/E test, the sample goes through a derivatization process. Derivatization is the process in which the hydroxy and keto groups of the compounds to be tested – in this case, testosterone and epitestosterone – are replaced with trimethylsulfate. The purpose of derivatization is to make the molecules larger

[Footnote continued on next page]

The GC/MS test is performed using a Gas Chromatography/Mass Spectrometer ("GC/MS") instrument, which identifies different substances within a urine sample. The GC/MS instrument calculates the absolute levels of testosterone and epitestosterone by measuring the area under their respected peaks. The ratio of testosterone and epitestosterone, however, is measured using the absolute values. It should be noted that the GC/MS instrument cannot distinguish between synthetic and natural testosterone because synthetic and natural testosterone has the same retention time and mass.

b. The Operation of the GC/MS Instrument

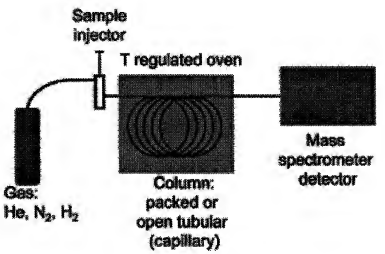
The GC/MS is composed of two major components: the gas chromatograph and the mass spectrometer.

The gas chromatograph is used to separate molecules by sending these molecules through a tube coated with a complex hydrocarbons, a reactive substance. Based on the chemical properties of each individual molecule, the molecule moves through the tube at different speeds. The amount of time each molecule takes to move though the gas chromatograph is considered the molecule's retention time. Separating the molecules permits the mass spectrometer portion of the machine to evaluate the molecules separately in order to identify them.

[Footnote continued from previous page]

and more volatile, which allows them to be tested more easily and therefore more accurately. Incomplete derivatization affects the reliability of the test results.

The mass spectrometer measures the individual molecules by breaking each molecule into ionized fragments. Once broken into ionized fragments, the mass spectrometer measures the abundance of the ions, also called a response, using each ionized fragment's mass to charge (m/z) ratio.



The GC/MS test produces a series of documents called chromatographs. A chromatograph is simply a graph with time on the X-axis and abundance, or quantity, on the Y-axis. Chromatographs can be particular to one specific ion or a spectrum, a range, of ions.

The specific GC/MS testing method is well illustrated at http://www.unsolvedmysteries.oregonstate.edu/GCMS_05.shtml, see exhibit GDC0247-0248. In pertinent part, the GC/MS process works as follows:

The urine sample is sent to chemistry. Chemistry serves several different purposes, such as, filtering the urine to remove solids and other unwanted materials and concentrate the urine, among others.

The prepared urine sample is injected into the GC/MS and the sample is carried by inert (non-reactive) gas (such as helium) through the instrument. The injection port is heated to 300° C to cause the chemicals to become gases.

The outer part of the GC is a very specialized oven. The column is heated to move the molecules through the column. Typical oven temperatures range from 40° C to 320° C. Inside the oven is the column which is a long (i.e., 30 meter) thin tube with a special polymer coating on the inside. Chemical mixtures are separated based on their volatility and are carried through the column by helium. Chemicals with high volatility travel through the column more quickly than chemicals with low volatility.

After passing through the GC, the chemical pulses continue to the MS. The molecules are blasted with electrons, which cause them to break into pieces and turn into positively charged particles called ions. This is important because the particles must be charged to pass through the filter.

As the ions continue through the MS, they travel through an electromagnetic field that filters the ions based on mass. The technician using the instrument chooses what range of masses should be allowed through the filter. The filter continuously scans through the range of masses as the stream of ions come from the ion source.

A detector counts the number of ions with a specific mass. This information is sent to a computer and a mass spectrum is created. The mass spectrum is a graph of the number of ions with different masses that traveled through the filter.

The data from the mass spectrometer is sent to a computer and plotted on a graph called a mass spectrum. The x-axis is mass and the y-axis is abundance or quantity.

Scientists can compare the mass spectrum of an unknown compound to a library of mass spectra of known compounds.

A "full spectrum" analysis considers all the "peaks" within a spectrum. Selective ion monitoring (SIM) looks only at a few characteristic peaks[12] (but requires looking at more than one characteristic peak) associated with a candidate substance. This is done on the assumption that at a given retention time, a set of ions is characteristic of a certain compound. When the amount of information collected about the ions in a given gas chromatographic peak is reduced, the sensitivity of the analysis goes up. Therefore, SIM analysis allows a smaller quantity of a compound to be detected and measured, but the degree of certainty about the identity of that compound is reduced as compared to a full spectrum analysis.

c. The Difference Between the Screening and Confirmation Methods

Additionally, there are two methods used at LNDD for determining the T/E ratio. One method is called the screen and the other is called the confirmation method. The screen and confirmation methods differ materially in several ways. First, the confirmation uses calibration curves for the semi-quantification of T and E. Second, the confirmation is done in triplicate, with a mean of the three samples used as a final result whereas the screen involves only a single workup and injection. Finally, the method file

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[12] Characteristic peaks are also referred to as diagnostic ions.

for the GC/MS run is different, including differences in, among other things, the dwell times spent on each ion.

d. The A Sample Testing Results: A Summary

LNDD conducted multiple GC/MS tests on Mr. Landis' A samples in the following order: one screen test, two confirmation tests, and lastly, another screen test. On July 21, 2006, the LNDD performed the first screen GC/MS test on the A sample. Exhibit 54. On July 24, 2006, LNDD conducted a confirmation GC/MS test. Exhibit USADA0054. This confirmation GC/MS test was rejected. As a result, on July 22, LNDD conducted a second GC/MS confirmation test failed. Exhibit USADA0101. Despite having performed a screen and two confirmation GC/MS tests, LNDD rather curiously conducted a second screen test on the A sample on July 25. Exhibit USADA0057.

The result of the first screen GC/MS test indicated a T/E ratio of 4.9:1. *See* Exhibit USADA0054. Documents associated with this test stated that there was inhibited derivatization. *See* Exhibits USADA0054 – 0056. The results of the first confirmation GC/MS test measured a T/E ratio of 10.7:1. *See* Exhibits USADA0092, 0223). According to USADA, the first confirmation test had weak measurements for the methyltestosterone and was disregarded. See USADA Pre-Hearing Brief at page 7. The second confirmation GC/MS test measured a T/E ratio of 11.4:1. Exhibit USADA0101. And, the second screen GC/MS test had a T/E ratio of 5.1:1. Exhibit USADA0057.

Curiously, the first screen test and second confirmation T/E test show testosterone concentration at approximately the same levels; however, the epitestosterone measured in

the second confirmation T/E test is less than one half of that measured in the first screen. *Compare* Exhibit USADA0057 to Exhibit USADA0101.

	T/E Ratio	Testosterone	Epitestosterone
Screen 1	4.9	44.9	10.1
Confirmation 1	10.7	127.4	13.0
Confirmation 2	11.4	45.5	3.9
Screen 2	5.1	36.8	8.2

e. The B Sample Testing Results: A Summary

Unlike the A sample, LNDD performed only one GC/MS test on the B sample using the confirmation method. Further, inconsistent with its testing procedures with the "A" sample, LNDD performed this one GC/MS test in triplicate. *Compare* Exhibit USADA0084 and Exhibit USADA0272. The first "B" sample GC/MS test measured a testosterone level of 46.8 and his epitestosterone at 4.4 with a T/E ratio of 10.9. See Exhibit USADA0288. And, the second GC/MS measured testosterone at 45.6 and his epitestosterone at 4.3 with a T/E ratio of 11. The third T/E test measured Mr. Landis' testosterone at 44.6 and his epitestosterone at 4.1 with a T/E ratio of 11.1. When the three GC/MS test results are averaged together, the single GC/MS test conducted on the B sample measured Mr. Landis' testosterone at 45.7, his epitestosterone at 4.1, and a T/E ratio of 11.

	T/E Ratio	Testosterone	Epitestosterone
B(1)	10.9	46.8	4.4
B(2)	11	45.6	4.3
B(3)	11.1	44.6	4.1
B(avg)	11	45.7	4.2

Before commencing the B sample GC/MS test, LNDD performed a degradation test. *See* Exhibit USADA0272, (line 8 of the sequence file for the "B" confirmation). This test resulted in a finding that the concentration of free epitestosterone to its glucuroconjugates was 7.7%. Exhibit USADA0283.

f. LNDD Violated ISL Standards At Every Step Of Its GC/MS Analysis

LNDD's performance of the GC/MS analysis repeatedly violated ISL standards, beginning with the preparation of the documentation and continuing through to the confirmation process. These repeated violations render all of these results, including the longitudinal analysis, utterly worthless. While USADA in fact concedes that some of LNDD's work is "not . . . consistent with best practice," *see* USADA Pre-Hearing Brief, at 76, USADA glosses over the many ISL violations detailed below. These include:

1. LNDD violated the ISL when it prepared the GC/MS documentation;

2. LNDD violated the ISL requirement to conduct a confirmation analysis using more stringent methods;

3. LNDD violated the ISL by wrongly identifying deuterated androsterone in the confirmation process;

4. LNDD violated the ISL requirement by failing to run the required calibration controls;

5. LNDD violated the requirement to verify the accuracy of calibration curves;

6. LNDD violated the requirement that no testing should be done on degraded urine samples; and

7. LNDD violated the ISL requirement that prohibits matrix interference in the chromatograms;

Any one of these ISL violations would be sufficient to invalidate the GC/MS results, but taken together, these violations demonstrate a consistent pattern of incompetence that infects the credibility of all the test results.

(i) LNDD'S LABORATORY DOCUMENTATION ERRORS

LNDD's GC/MS test results are only as reliable as the operators that perform them and the machinery on which they are performed. In fact, operators and other laboratory

personnel are required to have a "thorough knowledge of the[ir] responsibilities" to ensure that the test results are performed in a reliable method. ISL 5.4.2.2, Exhibit WADA0079-0135. In addition, all supervisory personnel are required to have a thorough understanding of, *inter alia*, quality control procedures, chain of custody procedures, and proper remedial actions necessary to respond to analytical problems that arise. ISL 5.4.2.6, Exhibit WADA0079-0135. While it is yet to be determined if the LNDD operators understood their responsibilities, the documentation provided by USADA undoubtedly evidences their failure to comply with simple, yet critical, provisions in the ISL, the WADA Technical Documents incorporated into the ISL, and ISO 17025.

(ii) LNDD'S LABORATORY DOCUMENTATION IS RIDDLED WITH ERRORS

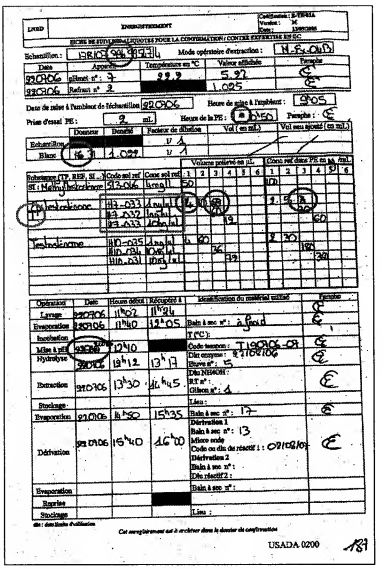
Proper documentation is essential to the accuracy and integrity of the anti-doping system. This is particularly true when it relates to proper sample identification, chain of custody and forensic corrections. Stringent rules protecting these interests are codified in both the WADA International Standards and in the underlying International Organization for Standardization rules governing laboratories.

WADA Technical Document 2003LCOC, Exhibit GDC0233, provides specific instructions concerning corrections to laboratory documents. The technical document requires that "[a]ny forensic corrections that need to be made to the comment should be done with a single line through and the change should be initialed and dated by the individual making the change." The Technical Document continues that "[n]o white out or erasure that obliterates the original entry is acceptable." *See* Exhibit GDC0233. The

ISO similarly provides that mistakes in the documents "shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside." But further yet, "[a]ll such alterations to records shall be signed or initialed by the person making the correction." *See* Exhibit GDC0304 (International Organization for Standardization ISO/EC 17025.4.3.2.3 (2005)).

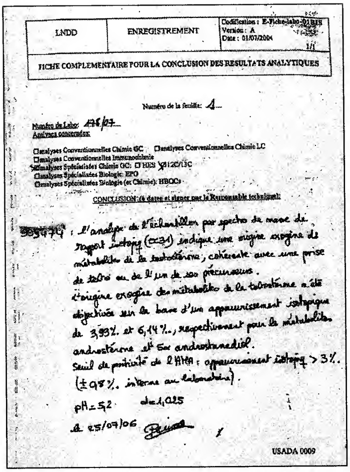
LNDD violated both the WADA technical document standard and the ISO standard on numerous occasions in conjunction with this testing. *See* Exhibits GDC0510-0513. Rather than list the thirty-nine WADA and ISO violations committed by LNDD, Mr. Landis has prepared a compilation of the errors as Exhibits GDC0510-0513. If requested by the Panel, Mr. Landis will provide further briefing concerning each individual violation.

The paradigm of LNDD's numerous violations, and its overall inept performance, is Exhibit 200. In Exhibit 200, there are no less than six improper cross-outs, an orphaned notation, incorrect notations of reference solutions for epitestosterone, and a likely incorrect notation for the reference solution for testosterone. Exhibit USADA0200 is shown below with the errors circled.



USADA 0200

Most troubling, at least five of LNDD's violations of the ISO and technical documents concern the sample number listed on the documents. As an example, in Exhibit USADA0009, LNDD violated the WADA and ISO provisions in changing the sample number from an unknown number to 995474 because the original sample number was made illegible and the operator did not initial and date the change. Exhibit USADA0009 is pictured below.



LNDD	ENREGISTREMENT	Codification : E-Fiche-labo-01818 Version : A Date : 01/07/2004 1/1

FICHE COMPLEMENTAIRE POUR LA CONCLUSION DES RESULTATS ANALYTIQUES

Numéro de la feuille: 4

Numéro de Labo: 176/07
Analyses concernées:

☐analyses Conventionnelles Chimie GC ☐analyses Conventionnelles Chimie LC
☐analyses Conventionnelles Immunochimie
☒analyses Spécialisées Chimie GC: ☐ HES ☒12C/13C
☐analyses Spécialisées Biologie: EPO
☐analyses Spécialisées Biologie (et Chimie): HBOCs

CONCLUSION: (à dater et signer par le Responsable technique):

995474 : L'analyse de l'échantillon par spectro de masse de rapport isotopique (IC31) indique une origine exogène des métabolites de la testostérone, cohérente avec une prise de testo ou de l'un de ses précurseurs.
L'origine exogène des métabolites de la testostérone a été objectivée sur la base d'un appauvrissement isotopique de 3,99‰ et 6,14‰, respectivement pour les métabolites androstérone et 5α androstanediol.
Seuil de positivité de l'AMA : appauvrissement isotopique > 3‰.
(±0,8‰ interne au laboratoire).
pH = 5,2 d = 1,025
Le 25/07/06 [signature]

USADA 0009

Accordingly, these violations evidence sloppy and careless laboratory operators, which are indicative of sloppy and careless testing, both in the preparation and actual performance of the test. If an operator cannot document properly the sample number or other critical values – and cannot comply with well established, basic ISO and technical document provisions – it is absurd to conclude that these same operators could perform highly technical, complex, and sensitive tests with the requisite accuracy to support the allegations here.

Moreover, USADA's argument that these violations are not sufficient to shift the burden is specious, at best. USADA's position - that the Panel should disregard these documentation errors because while they may not be best practice, they are not ISL violations - is telling of USADA's and LNDD's questionable commitment to accuracy. When leveling such a serious allegation as in this case, Mr. Landis submits that

adherence to best practices, whether or not required by the ISL, is necessary. That USADA ignores blatant documentation errors that directly affect the test results under the guise that such errors are meaningless because the ISL does not specifically prohibit them further establishes that USADA is not pursuing this action to obtain justice.

Nevertheless, despite USADA's disingenuous representations, ISO violations do rise to the level of an ISL violation because all ISO 17025 provisions related to testing and management are incorporated into the ISL. Indeed, section 5.1 of the ISL specifically incorporates all portions of ISO 17025. It states that "[a]ny aspect of testing or management not specifically discussed in this document [ISL] *shall* be governed by ISO/IEC 17025." Exhibit WADA0079-0135. The ISO violations cited by Mr. Landis' below are clearly relevant to the testing or management of Mr. Landis' Stage 17 sample.

Even if the ISO provisions were not incorporated into the ISL, which they are, Technical Document 2003LCOC sets forth similar procedures to the ISO regarding the proper procedures to correct mistakes in documents. Exhibit GDC0233. Accordingly, notwithstanding USADA's misleading assertions, LNDD's documentation violated the ISL and a technical document. As such, these violations suffice to satisfy Mr. Landis' burden of establishing deviations from the applicable rules. USADA, however, cannot overcome its stringent burden that, by a comfortable satisfaction, these gross departures from applicable rules did not affect Mr. Landis' test results. Moreover, the cumulative effect of these errors, coupled with the other errors discussed in this brief, establish that LNDD's test results are not worth the paper they are printed on.

(iii) SOME LABORATORIES NEVER LEARN: THE LANDALUCE / SAME OPERATOR ERROR

It is of critical importance that the same operator is not involved in the testing of both the "A" and "B" samples. A different analyst *must* perform the "B" analytical procedure than the analyst who performed the A analytic procedure. *See* Exhibit WADA0079-0135, at 5.2.4.3.2.2 (2004). Indeed, failure to comply with this provision is sufficient grounds to dismiss the anti-doping violation because the burden on the anti-doping agency to establish that such a departure from the rules did not affect the test results is nearly impossible. Landaluce, Exhibit GDC0161-0218.

There is significant evidence in the documents provided by USADA that Operator 18, Esther Cerpolini, was involved in the analytical testing for both the "A" and "B" sample, thus violating ISL 5.2.4.3.2.2, exhibit WADA0079-0135. The documents indicate that Ms. Cerpolini played a major role in the analysis of the "A" Sample. *See* Exhibit USADA0253. And, the documents establish that Ms. Cerpolini played several roles in the analysis of the "B" Sample. For example, she thawed the sample and may have calculated the for-specific-gravity concentrations for the GC/MS test. Exhibits USADA00253, 0258. Additionally, Ms. Cerpolini had the "B" sample in her custody for approximately an hour and forty-five minutes. Exhibit USADA0254.

USADA provides a self-serving representation that Ms. Cerpolini did not partake in the analytical testing of the "B" sample; however, USADA refused to permit Mr. Landis to depose her to investigate her involvement in the testing of the "B" sample. Mr. Landis refuses to give credence to USADA's unsupported assertion that Ms. Cerpolini

was not involved in the analytical testing of the B sample. Nevertheless, based on the documents, Ms. Cerpolini appears to have been involved in the testing of the "A" and "B" sample analytical testing in direct violation of the ISL.

(iv) LNDD CANNOT EVEN ACCURATELY QUANTIFY ITS REFERENCE STEROID

LNDD set its measurement of uncertainty at 20% for testosterone and 30% for epitestosterone. *See* Exhibit USADA0288. In order to calibrate its equipment properly, LNDD added precisely measured amounts of testosterone and epitestosterone to a clean matrix, and ran tests against them with an internal reference standard. This reference standard, 17α-methyltesterone, is then used to help determine the accuracy of the lab's testing ability when measured against known amounts of testosterone and epitestosterone. In conducting this calibration, LNDD failed miserably. In Exhibit USADA0086, the "A" Sample calibration), one half of the measurements of testosterone and epitestosterone exceeded 20% error rates. In Exhibit USADA0207, the "A" Sample calibration, two out of three T/E ratios exceed 20% error rates. In Exhibit USADA0270, the "B" Sample calibration, every testosterone and epitestosterone measured value exceeds a 30% error rate against precisely spiked urines.

(v) LABORATORY BLINDING WAS A SHAM

A laboratory processing a sample should not know the identity of the athlete being tested to ensure that personal or other biases do not interfere with the proper handling of the sample. This common sense principle is codified in WADA International Standards for Testing 9.3.4, exhibit GDC0357, which mandates that "documentation identifying the

Athlete shall not be included with the *Samples* or documentation sent to the WADA accredited laboratory or as otherwise approved by WADA." And, WADA Guidelines for Urine Sample Collection further provides that "documentation identifying the Athlete shall not be included with the samples." *See* WADA Guidelines for Urine Sample Collection (2004) 5.14.6, exhibit GDC0391. In sum, anonymity of the source of a sample is required as a fundamental issue of fairness because it helps protect the athlete from such potential bias.

LNDD was provided with doping control forms where the athlete declarations were available. This, *ipso facto*, establishes an infringement of the WADA provision. By having the athlete's declaration, LNDD again possessed a document that identified sample 995474 as Floyd Landis. That there might be policy of including athlete declarations with the sample, it, nonetheless, is in direct contradiction to the WADA provisions.

As Mr. Landis has demonstrated that LNDD has deviated from a WADA IST, USADA must present affirmative evidence, to a comfortable satisfaction, that these gross deviations did not affect the testing results; a burden, given the totality of the errors, USADA cannot satisfy.

(vi) HAS LNDD EVEN READ WADA TD2003IDCR?

WADA technical documents set forth two different procedures by which screening analyses and confirmation analyses must be conducted. While conducting a screening analysis, WADA Technical Document 2004EAAS permits to test for abnormal T/E ratio using a single aliquot and a single ion (m/z 432). *See* Exhibit WADA0011-0021 ("The

T/E value is given by the peak area or peak height ratio of testosterone and epitestosterone . . . obtained by measuring the ion at m/q 432 by GC/MS Analysis . . . [T]he Screening Procedure which is normally conducted on a single aliquot . . .").

However, the confirmation of a purportedly elevated (1) concentration of testosterone, (2) concentration of epitestosterone or (3) TE ratio must be made conducted pursuant to WADA TD2003IDCR, *see* Exhibit GDC0396-0400 and carries a much higher standard. LNDD failed this standard. WADA Technical Document 2004EAAS, exhibit WADA0011-0022, which governs the reporting and testing of testosterone, epitestosterone, T/E ratio and other endogenous steroids, states:

> Confirmation of elevated T/E values, concentration of testosterone, epitestosterone or any other steroid metabolite under consideration is to be performed in triplicate. *The confirmation of the identity of any steroid reported with abnormal properties must be made (refer to technical document TD2003IDCR).* Appropriate calibration (e.g. calibration curve, deuterated standards, quality control samples) is to be included in the protocol of the Confirmation Procedure."

(emphasis added). WADA Technical Document TD2003IDCR describes this requirement as follows:

> Full scan mode. A full or partial scan is the preferred approach to identification. A partial scan may begin at an m/z value greater than any abundant ion due to the derivatizing agent or chemical ionization reagent.
>
> When a full or partial scan is acquired, all diagnostic ions[13] with a relative abundance[14] greater than 10% in the reference spectrum obtained from a

---

[13] "Diagnostic ion(s)" is defined in relevant part at TD2003IDCR as follows: "Molecular ion or fragment ions whose presence and abundance are characteristic of the substance and thereby may assist in its identification."

positive control urine, a Reference Collection sample, or a Reference Material must be present in the spectrum of the unknown peak. In addition, the relative abundance of three diagnostic ions shall not differ by more than the amount shown in Table 1 from the relative intensities of the same ions from that of a spiked urine, a Reference Collection sample, or a Reference Material . . . .

Selected Ion Monitoring[15] Mode. In some cases, it may be necessary to monitor selected ions in order to detect the substance at the Minimum Required Performance Limits. When selected ions are monitored, at least three diagnostic ions must be acquired . . . .

If three diagnostic ions with a relative abundance greater than 5% are not available, a second derivative shall be prepared, or a second ionization or fragmentation technique shall be used. The second derivative should yield different diagnostic ions. The second ionization technique must be based on a different physical principle, i.e., chemical ionization vs. electronic ionization and again should provide different diagnostic ions. It is not acceptable to utilize a technique that changes only the relative abundance of the same mass ions. In any case a minimum of two diagnostic ions must be present in each mass spectrum.

See Exhibit GDC0396-0400. Thus, on a confirmation analysis, WADA TD2003IDCR requires one of the following:

1. Full or partial scan showing the presence of all diagnostic ions greater than 10% in the reference spectrum obtained from a positive control urine, a Reference Collection sample, or a Reference Material. The full or partial

---

[Footnote continued from previous page]

[14] "Relative abundance" is defined in relevant part at TD2003IDCR as follows: "The abundance of a particular ion relative to the most abundant ion monitored expressed as a percentage."

[15] "Selected Ion Monitoring (SIM)" is defined in relevant part at TD2003IDCR as follows: "Acquisition of ions of one or more pre-determined discrete m/z values for specified dwell times."

scan should show 3 diagnostic ions with a relative abundance greater than 5%. If that cannot be achieved, then a second derivatization should be performed using a different technique, and showing different diagnostic ions, and with each derivatization showing the presence of at least two diagnostic ions.

2. Select Ion Monitoring, acquiring at least 3 diagnostic ions. If that cannot be achieved, then a second derivatization should be performed using a different technique, and showing different diagnostic ions, and with each derivatization showing the presence of at least two diagnostic ions.

See id.

In testing Mr. Landis' sample, it is clear that LNDD treated the screening and confirmation tests the same, screening for only a single diagnostic ion – the exact same diagnostic ion – used in the screening analysis. The following makes LNDD's violation of this rule readily apparent.

The Data Analysis Parameters for the first "A" Confirmation, *see* exhibit USADA0086, show the acquisition of a single diagnostic ion at m/z 432.40:

3) testosterone ( )

Ret. Time 19.32 min., Extract & Integrate from 18.82 to 19.82 min.

Signal	Rel Resp.	Pct. Unc.(rel)	Integration
Tgt 432.40			man27.e

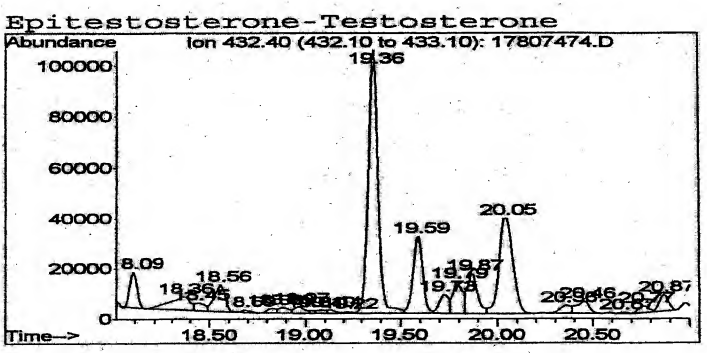
Lvl	ID	Conc (ng/ml)	Response
1		30.000	1557516
2		180.000	7052377
3		360.000	17023691

Qualifier Peak Analysis ON

Method: MAN27.M Mon Jul 24 17:15:54 2006 Page:2

USADA 0086

The chromatogram for the first "A" confirmation , *see* exhibit USADA0093, shows the acquisition of a single diagnostic ion at m/z 432.40:



The Data Analysis Parameters for the second "A" Confirmation, *see* exhibit 207, show the acquisition of a single diagnostic ion at m/z 432.40:

3) testosterone ( )

Ret. Time 19.31 min., Extract & Integrate from 18.81 to 19.81 min.

Signal Tgt 432.40	Rel Resp.	Pct. Unc.(rel)	Integration man27.e

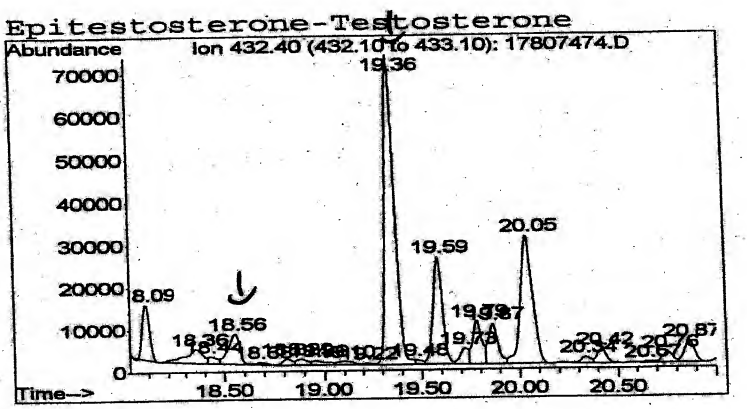
Lvl	ID	Conc (ng/mL)	Response
1		30.000	1359912
2		180.000	7964015
3		360.000	21495301

Qualifier Peak Analysis ON

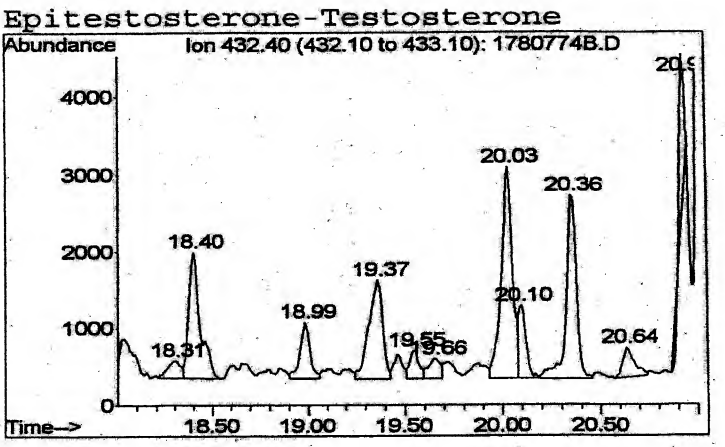
Method: MAN27.M Mon Jul 24 12:55:02 2006 Page:2

USADA 0207

The chromatograms for the second "A" confirmation, *see* exhibits USADA0213, 0215, show the acquisition of the same diagnostic ion at m/z 432.40:



(Exhibit USADA0213)



(Exhibit USADA0215)

The Data Analysis Parameters for the "B" Confirmation, *see* exhibit USADA0270, show the acquisition of a single diagnostic ion at m/z 432.40:

3) Testosterone (TR)

Ret. Time 19.30 min., Extract & Integrate from 18.80 to 19.80 min.

Signal Rel Resp. Pct. Unc.(rel) Integration
Tgt 432.40 man27.e

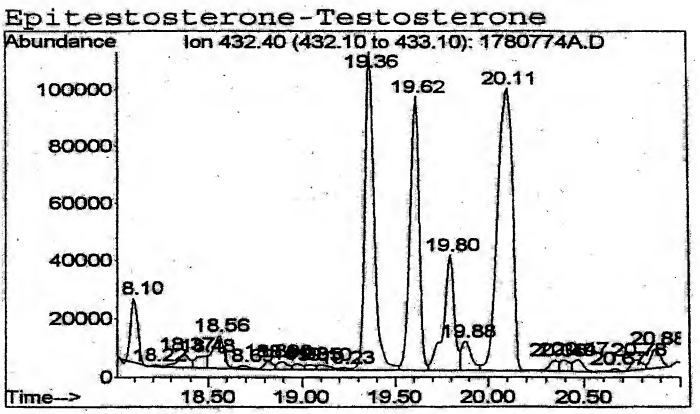
Lvl	ID	Conc (ng/mL)	Response
1		30.000	1845917
2		180.000	7860237
3		360.000	20557109

Qualifier Peak Analysis ON

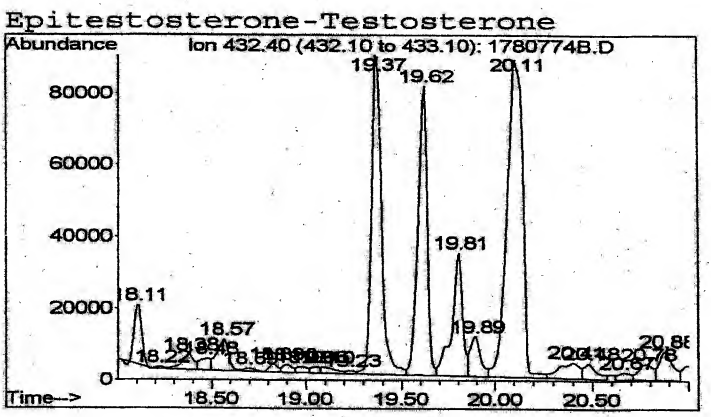
Method: MAN27.M Fri Aug 04 07:32:57 2006 Page: 42

USADA 0270

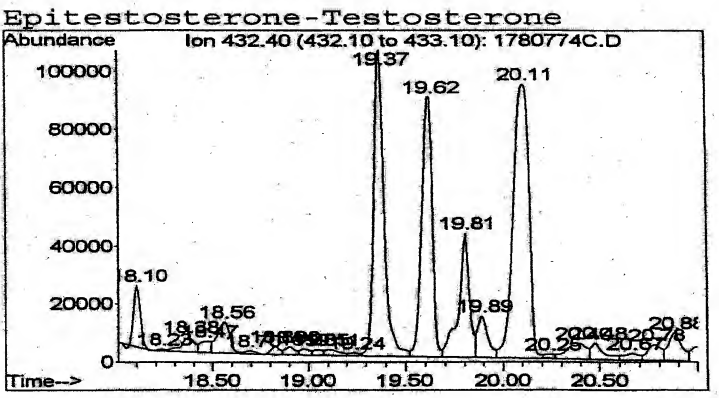
The chromatograms for the "B" confirmation, *see* Exhibits USADA0277, 0280, 0282, 0284, show the acquisition of a single diagnostic ion at m/z 432.40:



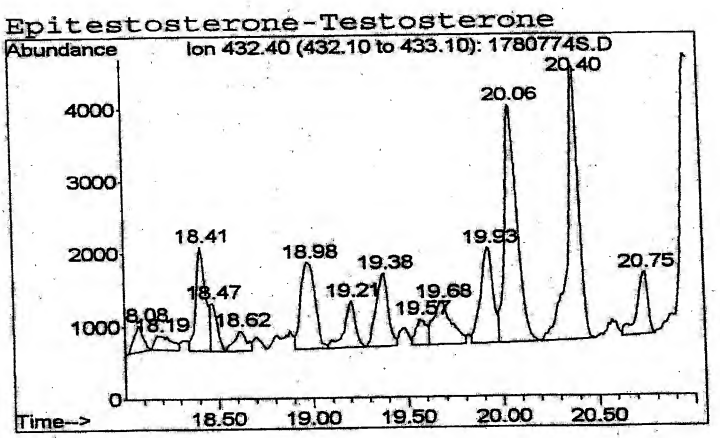
(Exhibit USADA0277)



(Exhibit USADA0280)



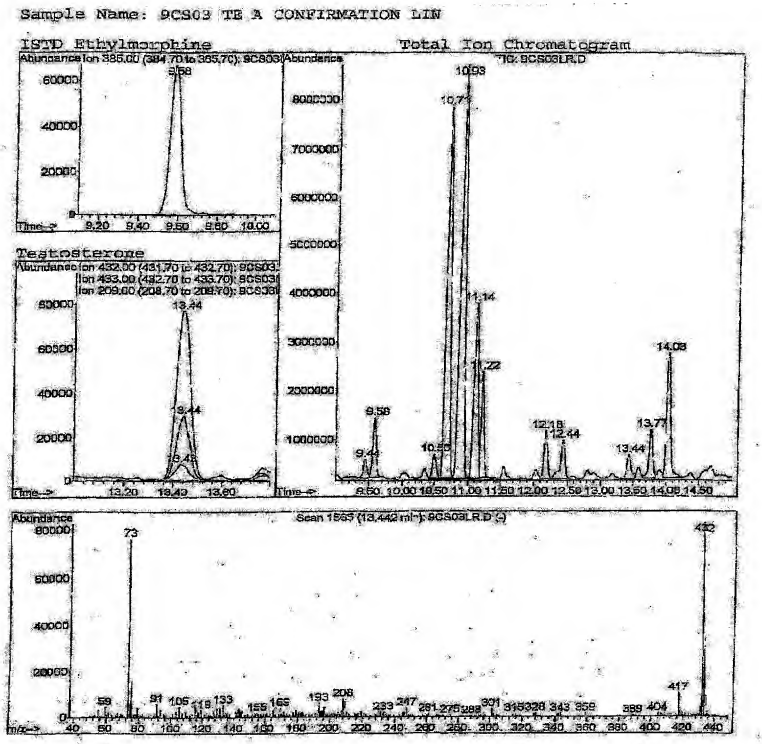
(Exhibit USADA0282)



(Exhibit USADA0284)

From the foregoing, LNDD clearly violated the applicable WADA scheme. Both the "A" confirmation and the "B" confirmation failed the controlling WADA Guidelines by acquiring only a single diagnostic ion for testosterone, and always acquiring the same diagnostic ion at m/z 432. LNDD never completed a full scan and never acquired 2, let alone 3, diagnostic ions for testosterone on any scan. All of the above are in violation of WADA TD2003IDCR, *see* Exhibit GDC0396-0400.

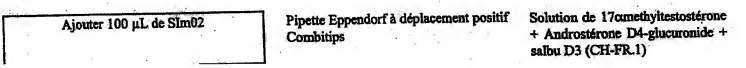
LNDD's failures are sharply contrasted with the proper confirmation method, as demonstrated by the UCLA Olympic Analytical Laboratory in another case completely unrelated to Mr. Landis. *See* Exhibit GDC0401 (Redacted):



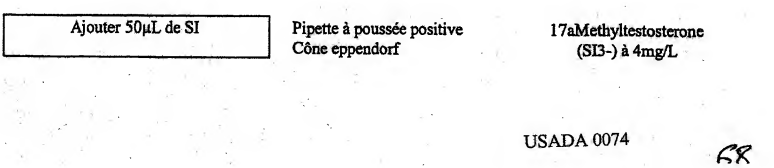
These unrelated laboratory documents show a proper confirmation method, utilizing a full scan, and an acquisition of 3 diagnostic ions for testosterone (at m/z 432, 433, and 209).

(vii) LNDD LOSES AN INTERNAL STANDARD: THE ANTITHESIS OF "PRECISE AND ACCURATE TESTING"

During the confirmation testing of Sample 995474, LNDD injected different internal reference standards for the purpose of (1) determining the ability of the equipment and testers to identify a known exogenous substance and (2) assisting with the quantification of unknown substances. On the screening analysis, LNDD added 3 such internal standards: 17α-methyltestosterone, androsterone D4-glucoronide and salbutamol D3.[16] *See* Exhibit USADA0037:



In contrast to the screening method, LNDD added only 17α-methyltestosterone as an internal standard on the "A" confirmation analyses. *See* Exhibit USADA0074:



See also Exhibit USADA0195:

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[16] D4 and D3 designate deuterated hydrogen. Deuterated molecules are often used as internal reference standards in GC/MS analysis because they create identifiable peaks that are not found naturally in urine.

Ajouter 50µL de SI	Pipette à poussée positive Cône eppendorf	17aMethyltestosterone (SI3-) à 4mg/L

USADA 0195

182

According to Exhibit USADA0057, LNDD on July 25, 2006, after the "A" confirmation had been completed, ran a separate aliquot of sample 995474:

D:\msd19\jul07\2507\17807474.D

Data File Path D:\msd19\jul07\2507\
Data File Name 17807474.D
Operator M45P35
Acq. Method File MAN06B_B.M
Sample Name 178/07 995474 H
Misc Info
Vial Number 2
Instrument Name MSD 19
Calibration Title Calibration des stéroïdes endogènes
Last Calibration Update Tue Jul 25 15:15:32 2006
Fichier recal utilise 25rcl01.D

Date : 25/07/06
Opérateur : IO

C [ ] HC [ ]

Résultats : Négatif [ ]
A vérifier [ ]

Remarques : Vial de conf. reinjecté
pour screening

#	Peak Type	Ret Time	Signal	Name	Target Response	Amount	Units
1)	*ISTD	17.14	301.3	Methyltestosterone	1,731,969	100	ng/ml
2)		12.38	438.4	Andro -D4 gluc	104,768	170	ng/ml
3)		0.00	372.3	Salbutamol -D3	0	0	ng/ml

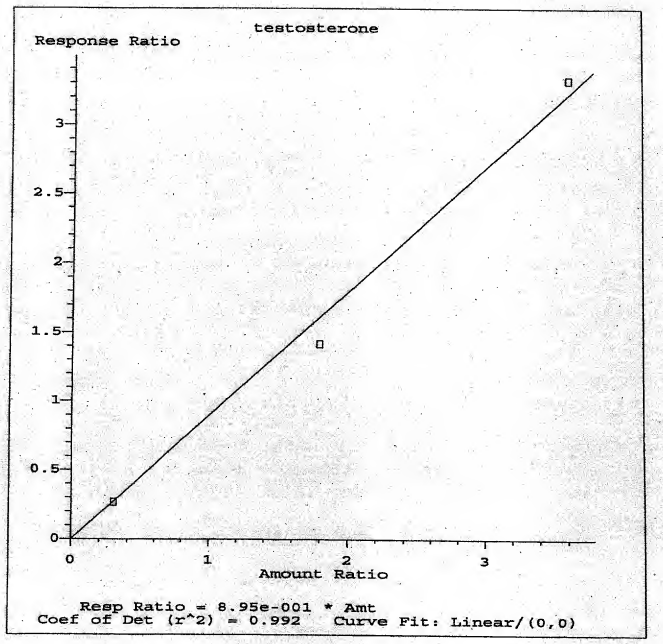
This appears to be a re-injection of a confirmation sample using the screening technique. As such, the procedure called for LNDD to add 3 internal standards: 17α-methyltestosterone, androsterone D4-glucoronide, and salbutamol D3. However, the testing failed to detect any of the salbutamol D3 that was added to the sample as an internal reference standard. This indicates that the test procedure was not operating properly, and that any results obtained are therefore unreliable. LNDD should have realized that this was a failed test, and should not have relied on the results in any way. This is because the results, for the reasons explained above, are unreliable and inaccurate.

(viii) LNDD DID NOT RUN THE REQUIRED CALIBRATION CONTROLS

WADA rules explicitly recognize that accurate identification and drawing of calibration curves is critical to accurate GC-MS analysis. TD2004EAAS, *see* Exhibits GDC0011-0022, requires any confirmation analysis for the T/E ratio to include appropriate calibration controls (*"Appropriate calibration (e.g. calibration curve, deuterated standards, quality control standards) is to be included in the protocol of the Confirmation Procedure.*") (Emphasis added). The manner in which LNDD conducted its calibration violated these requirements.

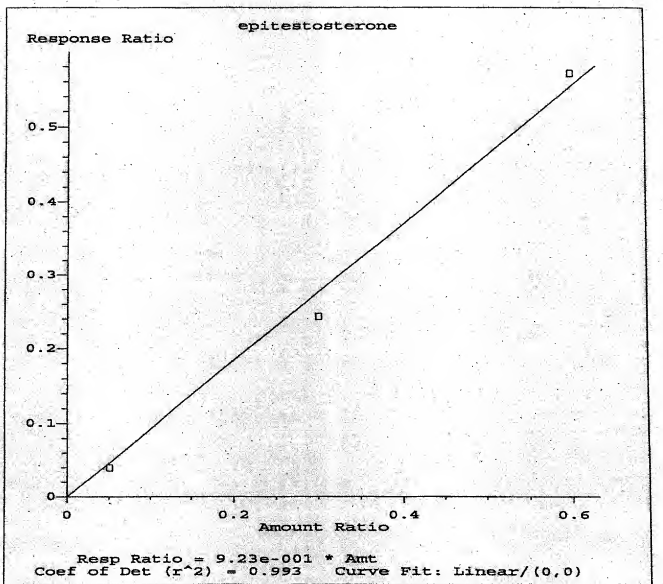
(ix) THE CALIBRATION CURVES: HOW NOT TO CONNECT THE DOTS

The estimates of the concentration of testosterone, epitestosterone, and the T/E ratio are made based upon the calibration curves. Those estimates are only as accurate as the calibration curves themselves. Here, LNDD drew its calibration curves using a 3-point calibration. *See, e.g.*, Exhibit USADA0088. This method plots only three known points on a graph, and then the technician draws the calibration curve to intersect those calibration points. The more calibration points are used, the more accurate the calibration curve. The use of a 3-point calibration curve is minimal at best. Even worse, LNDD failed to even draw the curve through the calibration points on many of the calibration curves. Starting with the first "A" confirmation analysis, both the testosterone and epitestosterone calibration curves are woefully inaccurate, as they fail to intersect the actual calibration points, *see* Exhibits USADA0088, 0089.



Method Name: D:\MSDCHEM\1\METHODS\MAN27.M
Calibration Table Last Updated: Mon Jul 24 17:15:46 2006

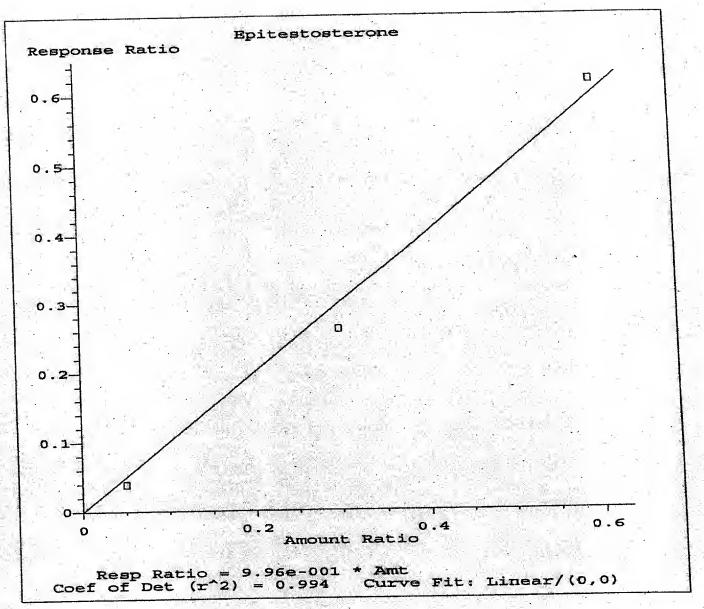
USADA 0088



Method Name: D:\MSDCHEM\1\METHODS\MAN27.M
Calibration Table Last Updated: Mon Jul 24 17:15:46 2006

USADA 0089

The lack of precision with which these calibration curves are drawn invalidates the estimates of testosterone, epitestosterone, or the T/E ratio from the first "A" sample confirmation analysis. On the second "A" confirmation analysis, the calibration curve for epitestosterone shows the same problems, *see* Exhibit USADA0209:



Method Name: D:\MSDCHEM\1\METHODS\MAN27.M
Calibration Table Last Updated: Mon Jul 24 12:54:54 2006

USADA 0209

Since this calibration curve is inaccurately drawn, none of the estimates of epitestosterone from the second "A" sample confirmation analysis are accurate; and as a result, none of the estimates for T/E ratio from the second "A" sample confirmation analysis are accurate. Given that the sample allegedly showed relatively low levels of epitestosterone, the inaccuracy of this calibration curve would have very large inaccuracies in the T/E ratio estimates.

(x) LNDD RAN NO CONTROL SAMPLES TO VERIFY THE ACCURACY OF THE CALIBRATION CURVES

A scientifically accepted and required method of verifying the accuracy of calibration curves is to run controls to verify the accuracy of the curves. Simply stated, a laboratory should run positive controls at known concentrations of testosterone and epitestosterone and plot them on the calibration curve, to determine if the curve is in fact accurate. LNDD ran no such controls, and therefore took no steps to verify the accuracy of its calibration curves. This is a violation of TD2004EAAS, which requires appropriate calibration to be included in the protocol of the Confirmation Procedure.

(xi) URINE SAMPLE DEGRADATION INVALIDATES THE T/E RATIO ANALYSIS

WADA rules carefully proscribe the level of degradation that may be present before a urine sample is not usable for testing purposes. Indeed, when bacterial activities in the urine are present, "the steroid profile parameters are worthless." *See* Geyer H., *et al.*, The Cologne protocol to follow up high testosterone/epitestosterone ratios. RADA (4), Proceedings of the 14th Cologne Workshop on dope analysis; Donike, M., et al, eds. 113. (1997), exhibit GDC0431-0450 In particular, the lowering of the T/E threshold from 6 to 4 requires a "careful examination of potential markers of urine degradation." *See* Molaioni, F., *et al.* Urine stability, steroid profile and T/E ratio: towards an index of sample degradation. RADA (13). Proceedings of the Cologne Workshop on Dope Analysis. 187. (2006), exhibit GDC0425-0430 Pursuant to WADA Technical Document TD2004EAAS, *see* Exhibit WADA0011-0021:

> The urine Sample is not collected under sterile conditions, and where the circumstances are favourable, the microbes present in the Sample can cause changes to the profile of the urinary steroids. Initially there is cleavage of the glucuronides and sulfates followed by modifications of the steroids' structure by oxido-reductive reactions. To report an Adverse Analytical Finding of an elevated T/E value, testosterone or epitestosterone concentration or any other endogenous steroid parameters, the concentration of free testosterone and/or epitestosterone in the specimen is not to exceed 5% of the respective glucuroconjugates."

Here, the test for degradation on the B Sample showed that the ratio was 7.7% – 2.7% greater than the allowable 5% limit. LNDD should have performed this test on the A Sample pursuant to the WADA Technical Document, but, for some unknown reason, did not.

In the reporting of the "B" sample confirmation results, the concentration of free testosterone and/or epitestosterone in the specimen is shown as follows:

	Testosterone	Epitestosterone	T/E Ratio
USADA0288 (analysis of glucoroconjugates)	61.7	5.7	11.0
USADA0283 (analysis of free testosterone)	1.22	0.44	2.8
Percentage of free testosterone to glucoroconjugates	2.0%	**7.7%**	

As the concentration of free epitestosterone in the specimen exceeds 5% of the respective glucoroconjugates, the result cannot be used pursuant to TD2004EAAS.

In response to this argument, USADA claims that the measure of free epitestosterone is too low to be reliable for this type of determination of degradation. In response, it is submitted that:

a. LNDD raised no such issue in the Laboratory Documentation package when it identified the alleged concentrations of epitestosterone as being 0.44 ng/mL, exhibit USADA0283;

b. LNDD not only reported the concentration level of free epitestosterone, but they reported it to the hundredth of a nanogram - certainly, measurements quantified down to the hundred-billionth of a gram per milliliter are inconsistent with a later claim that those measurements cannot be accurately quantified;

c. If the free epitestosterone were too low to accurately quantify, then these measurements should not have been reported at all, or should have been reported with a disclaimer as to their accuracy (which they were not); and

d. USADA's reference to the WADA minimum required performance level for the detection of epitestosterone as being 2 ng/mL is irrelevant, as USADA has refused and failed to provide any documentation related to the determination by LNDD of a 30% measure of uncertainty for epitestosterone concentration (see October 16, 2006 document demand, number 33), which necessarily would include data related to lower limit of detection.

Furthermore, USADA's allegation that degradation would lead to a higher reported concentration of epitestosterone, and therefore a lower reported T/E ratio, is completely unsupported and should be disregarded as speculation.

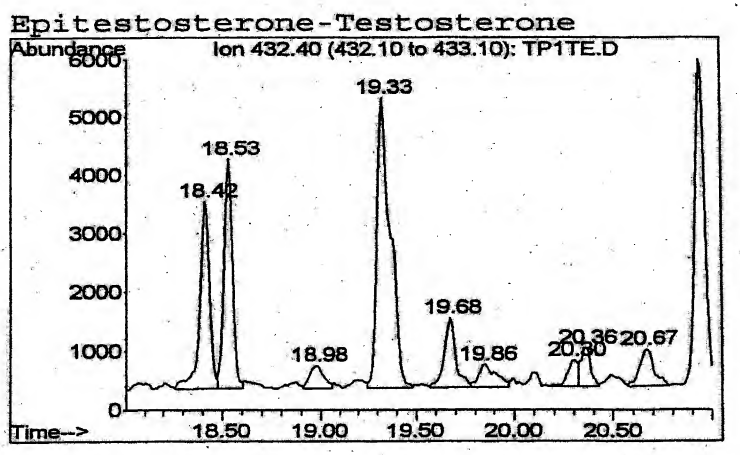
(xii) BAD CHROMATOGRAMS EQUALS UNRELIABLE RESULTS

The accuracy of the GC/MS results depends upon the ability of lab personnel to operate the GC/MS instrument so that target compounds are not confused with other, unrelated substances. This critical requirement is codified in WADA ISL sections 5.4.4.2.1 – 5.4.4.2.2, exhibit WADA0079-0135, which require, for both threshold and non-threshold substances, that the confirmation method avoids interference in the detection of Prohibited Substances (or their metabolites) by components of the urine sample matrix. These interferences – also known as matrix interferences – destroy the accuracy of both the identification and quantification of prohibited substances or their metabolites. The reason that matrix interferences create this inaccuracy is because the size and shape of chromatograms are affected when the target substances are confused with other substances. When these target substances are confused, the chromatograms take on additional area and height that gives a false reading as to the identification and amount of the target compound.

In this case, matrix interferences are present in a number of chromatograms, in the form of peaks that show interference -- many of the peaks show right and left discernable shoulders, which are evidence of unacceptable coelution and other interferences.

Coelution is the process by which a target compound has overlapped with another compound, thereby rendering the chromatogram unreliable.

For example, exhibit USADA0100 shows an unacceptable right shoulder peak for testosterone at a retention time of 19.33:

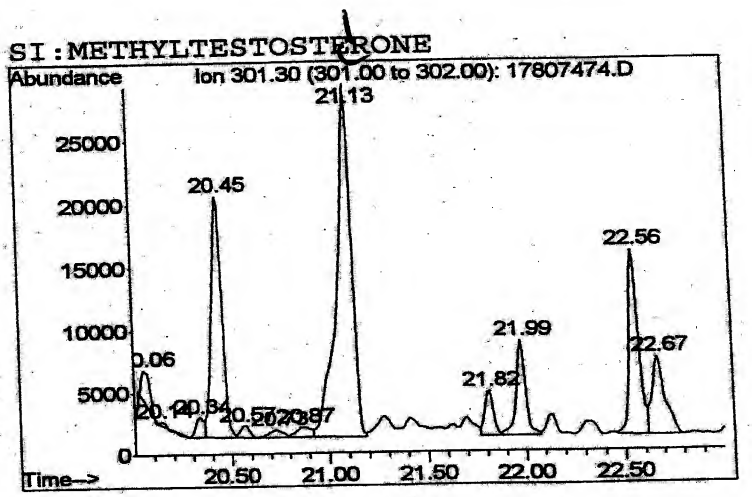


This coelution makes quantification of a target substance, like testosterone or epitestosterone, completely unreliable, and the T/E ratio completely unreliable. That is precisely what happened with the Stage 17 Sample.

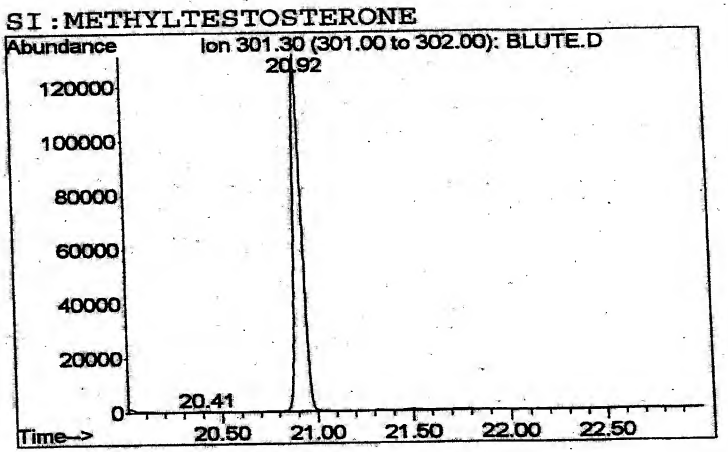
(xiii) RETENTION TIMES REALLY MATTER

Appropriate monitoring of retention time values is another critical component of properly performing the GC/MS testing. Several different molecules can have the same retention time. Because of this, it is critical the GC/MS instrument properly identify the retention time of the target molecules. This fundamental principle is embodied in

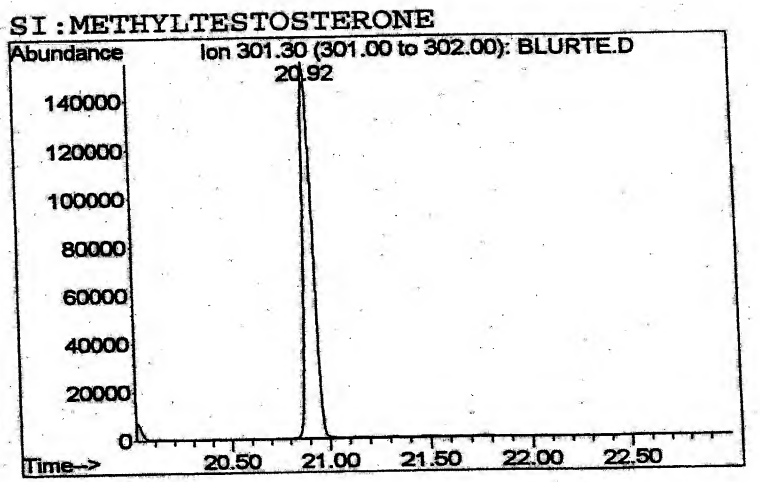
WADA Technical Document TD2003IDCR, which specifies that "For capillary gas chromatography, the retention time (RT) of the analyte shall not differ by more than one (1) percent or ±0.2 minutes (whichever is smaller) from that of the same substance in a spiked urine sample, Reference Collection sample, or Reference Material analyzed contemporaneously." This ISL standard was violated here. In the "A" confirmation sample, the RT of the internal standard of sample 995474 has a greater variation than is allowed when compared to virtually every control sample run contemporaneously. In sample 995474, the RT for the internal standard (methyltestosterone) is shown at 21.13 minutes, exhibit USADA0213:



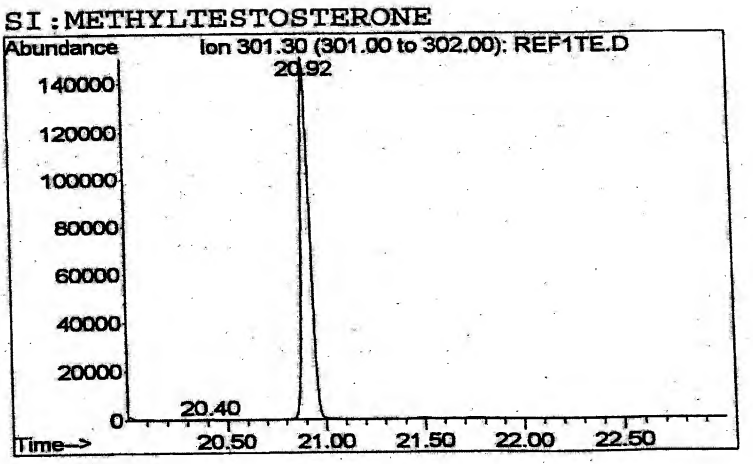
The retention time for the internal standard of sample 995474 varies by more than 0.2 minutes from that shown on the blank urine contained in vial 9, which showed a retention time of 20.92 minutes exhibit USADA0210:



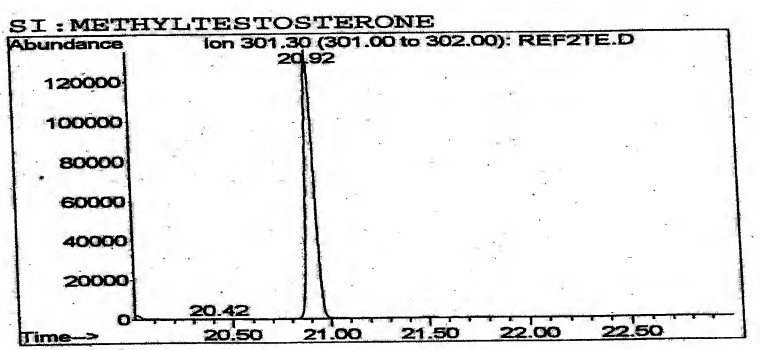
The retention time for the internal standard of sample 995474 varies by more than 0.2 minutes from that shown on the blank urine contained in vial 12, which showed a retention time of 20.92 minutes, exhibit USADA0211:



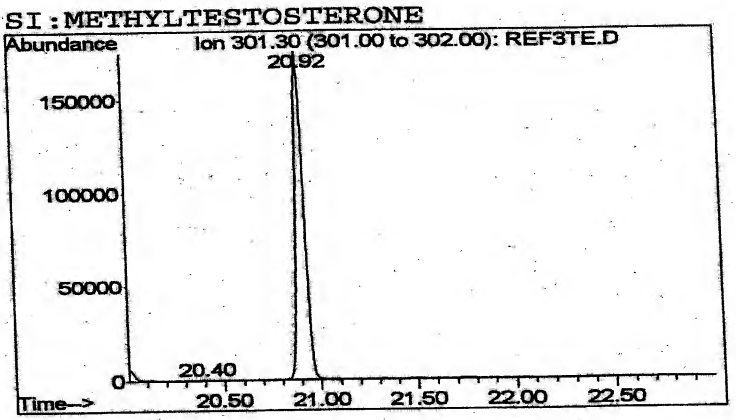
The retention time for the internal standard of sample 995474 varies by more than 0.2 minutes from that shown on the positive control urine contained in vial 13, which showed a retention time of 20.92 minutes, exhibit USADA0216:



The retention time for the internal standard of sample 995474 varies by more than 0.2 minutes from that shown on the positive control urine contained in vial 14, which showed a retention time of 20.92 minutes, exhibit USADA0217:



The retention time for the internal standard of sample 995474 varies by more than 0.2 minutes from that shown on the positive control urine contained in vial 15, which showed a retention time of 20.92 minutes, exhibit USADA0218:



As demonstrated above, the retention time of the internal standard of sample 995474 has an unacceptable variance from every contemporaneous positive control urine as well as most of the contemporaneous blank urines. This indicates a problem with the analysis of sample 995474, and a non-compliance with the applicable WADA guidelines, such that the results cannot be relied upon.

1) USADA's Arguments Miss the Mark

In its attempt to defend LNDD's errors, USADA makes a number of other contentions that misrepresent the quality of LNDD's work and ignore the critical errors LNDD committed. For example, USADA makes the misleading claim that the variability in T/E ratios measured on the screening analyses (ratio of 4.9 – 5.1) and the confirmation

analyses (10.9 – 11.4) does not matter, because the figures are derived using different testing methods. *See* USADA Pre-Hearing Brief at page 75.

First, USADA fails to explain how a greater than 200% variability in measurement of the same sample can possibly be acceptable, even if different techniques are used. USADA thus admits that LNDD's various techniques can result in a value that is over twice that of another value in testing the same urine.

Second, this greater than 200% error rate is significant, given that USADA's longitudinal analysis is comprised of primarily screening data, which it then compares to the confirmation testing data on sample 995474. The nonsensical nature of USADA's "two different methods" argument is borne out by WADA's explicit approval of the use of both screen data and confirmation data in a longitudinal T/E analysis. See Exhibit WADA0011-0021, at 4. This rule is set forth as:

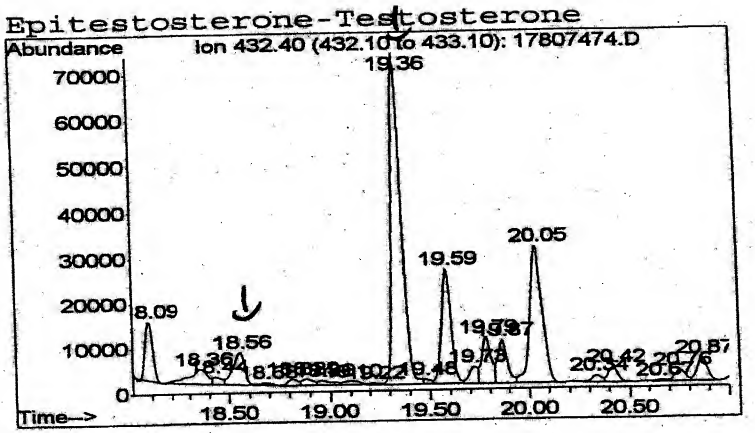
> In males, the individual T/E values have been shown to vary from their mean value by less than 30% (screening values). . . .
>
> If the suspicious test result, when compared to the basal value using appropriate statistical evaluation is found to be significantly different, that will constitute a proof of the administration of a source of testosterone. It is understood that the basal value may be calculated from previous screening test results. **The comparison of screening results and confirmed results is acceptable.** (Emphasis added).

Given that WADA Technical Document (1) would determine an Adverse Analytical Finding based upon a variability of T/E ratio exceeding 30%, and (2) allows comparison of screening results to confirmation results as part of the longitudinal analysis, then WADA **must have intended** that variability between screening results and confirmation results of the same sample cannot exceed 30% - otherwise, comparison of

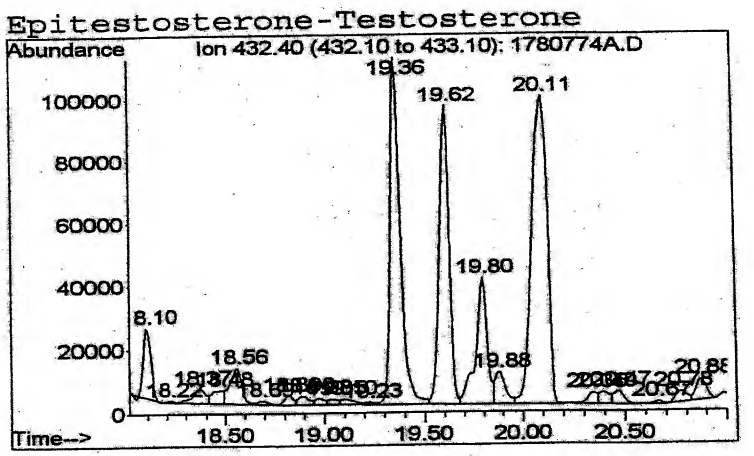
the variability of results of the single sample 995474 (4.9 compared to 11.1) would constitute a doping offense. Such a holding would be preposterous. Lastly, it can not be ignored that in this case, USADA is comparing screening to confirmation values in its T/E longitudinal study. *See* USADA Pre-Hearing Brief, at page 70, figure 20.

Another example of USADA's silly defenses are as follows. In response to a portion of Mr. Landis' discovery brief (when he had no meaningful discovery), USADA attempts to rebut the criticism of LNDD's botched screening analysis of Sample 995474. *Id.* at page 75. Indeed, USADA even admits that this screening test is botched. USADA seeks to have the Panel ignore this sloppy and unsupportable work by claiming that "this coeluting peak for epitestosterone was substantially eliminated during the more rigorous A and B sample confirmation method which produced more accurate results." *Id.* In making this claim, USADA points to a coeluting peak that was present on the left shoulder of the epitestosterone chromatogram.

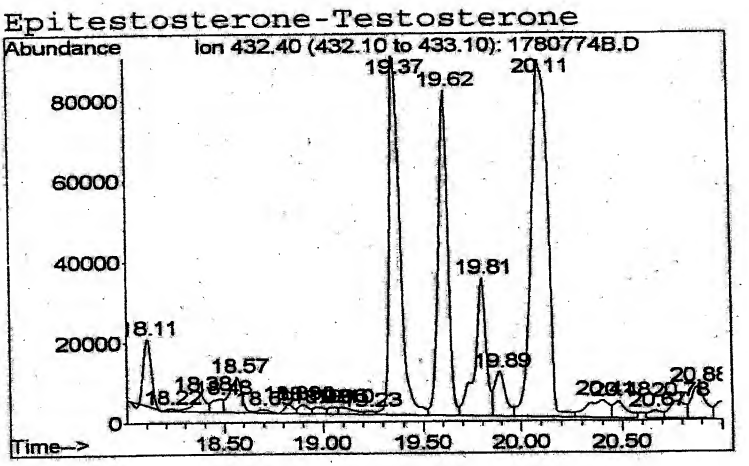
What USADA does not tell the Panel is that the confirmation analysis displayed precisely the same co-elution problem. See Exhibit USADA0213, "A" confirmation, with coeluting epitestosterone peak (claimed to appear at a retention time of 18.56):



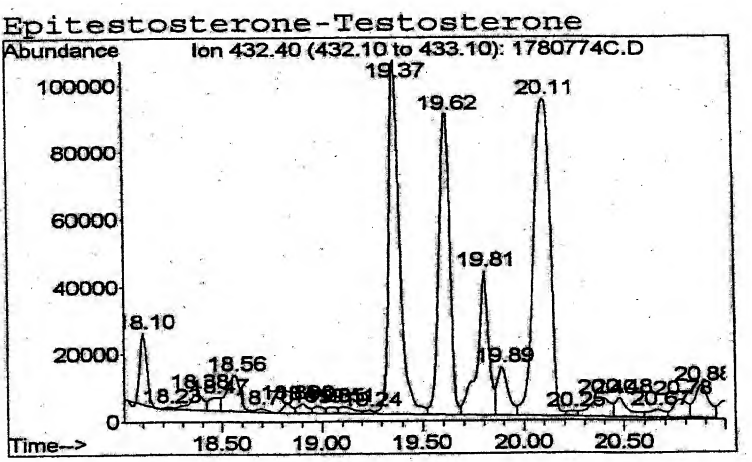
See also, Exhibit USADA0277, "B" confirmation First Replicate, with coeluting epitestosterone peak (claimed to appear at a retention time of 18.56):



See also, Exhibit USADA0280, "B" confirmation Second replicate, with coeluting epitestosterone peak (claimed to appear at a retention time of 18.57):



See also, exhibit USADA0282, "B" confirmation 3rd replicate, with coeluting epitestosterone peak (claimed to appear at a retention time of 18.56):



USADA claims that the screening analysis is not accurate because of a coeluting left shoulder peak on the epitestosterone peak, but the confirmation analyses are no better. This means that the confirmation analyses are also unreliable and inaccurate. It also means that the justification provided by USADA for the gross variability in the T/E ratio between the screening analyses and the confirmation analyses is not convincing. In other words, USADA has provided no supportable justification for this gross variability. The end results, similar to all of the other demonstrated problems, is that the test results related to testosterone, epitestosterone and T/E ratio are inaccurate and unreliable.

3. GC/C/IRMS Carbon Isotope Ratio Test: Incompetence Turns to Fraud

The issues surrounding the Carbon Isotope Ratio Test are not fully set forth here pursuant to the order of the Panel allowing Mr. Landis to supplement his brief after review of the Standard Operating Procedures, received on the night of April 24, 2007, and the Electronic Data Files, which Mr. Landis still has not yet received. This evidence is central to Mr. Landis' analysis of the LNDD's IRMS data and conclusions, and he will supplement this brief as soon as USADA has complied with its discovery obligations. Further, Mr. Landis wishes to put the Panel on notice that on the morning of April 26, he became aware that LNDD had willfully destroyed and altered the critical EDF evidence in this case, outside of the presence of the Panel's expert. While the facts are unclear at this moment, Mr. Landis will provide the Panel with further detail on this spoliation of evidence as the scope and breadth of the misconduct of LNDD and possibly other individuals from USADA's defense team becomes better understood.

a. The Theory of The Carbon Isotope Ratio Test

Given the inconclusiveness of the T/E test, WADA rules require that the T/E test, standing alone, is insufficient to support a finding of exogenous testosterone. WADA instead requires additional evidence of doping. *See* Exhibit WADA0011-0021. Indeed, WADA currently requires that any sample with a T/E ratio greater than 4:1 be examined further for possible evidence of exogenous testosterone administration. The 4:1 ratio represents a recent change from the prior 6:1 ratio. *See* Exhibit GDC0404-0424 (2005 WADA Prohibited List). There are various confirmation tests performed by WADA-accredited laboratories.

Although WADA-accredited laboratories perform various confirmation test, LNDD's confirmation test is the IRMS test. To understand the IRMS test, however, some background is required: Generally, molecules are composed of atoms. Biological molecules are composed primarily of Carbon, Oxygen and Hydrogen atoms. Carbon, in its basic form, is an atom composed of six electrons, six protons and six neutrons. In nature, however, all elements have one or more stable isotopes. An isotope is an atom that has "extra" neutrons. In the case of carbon, it has two staple isotopes: ^{13}C and ^{12}C. ^{13}C is a stable isotope that has one "extra" neutron over ^{12}C. The actual carbon isotope makeup of any individual will vary based on his or her diet. The same is true for plants. As it turns out, the particular plants (mostly soy) used for the building blocks of synthetic or pharmaceutical testosterone are particularly low in ^{13}C, especially when compared to the levels found in most humans.

The IRMS test is performed using a GC-C-IRMS instrument, which measures the ratio of $^{13}C/^{12}C$ in a target analyte. The theory behind the test is that synthetic testosterone, which is usually soy-based, will be depleted in carbon 13. To account for individual variabilities in things such as diet, which can affect the $^{13}C/^{12}C$ ratio, the test compares the $^{13}C/^{12}C$ ratio of a testosterone metabolite that is believed to be affected by exogenous testosterone[17] to the $^{13}C/^{12}C$ ratio of an endogenous reference compound that is believed not to be affected by exogenous testosterone[18]. By comparing the difference in the $^{13}C/^{12}C$ ratio between a testosterone metabolite and an endogenous reference compound ("ERC"), the IRMS test can, if performed properly, indicate the likelihood of testosterone being from an exogenous source.

In theory, for any individual at any one time the $^{13}C/^{12}C$ ratio of an ERC should be identical (or very close) to that of a testosterone metabolite. If a person is using exogenous testosterone, however, there will be a detectable and significant difference between the $^{13}C/^{12}C$ ratio in a testosterone metabolite and an ERC. In other words, if a person is taking exogenous testosterone, his or her $^{13}C/^{12}C$ ratio for a testosterone metabolite will be different than the ratio for an ERC.[19]

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17 Such as Androsterone, Etiocholanolone, 5α-Androstanediol, and 5β-Androstanediol.

18 Such as 11-Ketoetiocholanolone and 5β-Pregnanediol.

19 A good summary of the IRMS theory is provided at Maitre et al., Urinary Analysis of Four Testosterone Metabolites and Pregandiol by Gas Chromotography-Combustion-

[Footnote continued on next page]

Once the $^{13}C/^{12}C$ ratio, also referred to as the $\delta^{13}C‰$ value, for the testosterone metabolites and the ERC's are calculated, the positivity criteria mandated by WADA is as follows:

> The results will be reported as consistent with the administration of a steroid when the $^{13}C/^{12}C$ value measured for the **metabolite(s)** differs significantly i.e. by 3 delta units or more from that of the urinary reference steroid chosen. In some *Samples*, the measure of the $^{13}C/^{12}C$ value of the urinary reference steroid(s) may not be possible due to their low concentration. The results of such analysis will be reported as "inconclusive" unless the ratio measured for the metabolite(s) is below -28‰ based on non-derivatized steroid.

See Exhibit WADA0011-0021, at 3.

b. The "A" Results: A Summary

On July 24, 2006, LNDD conducted the IRMS test on Mr. Landis' "A" sample.[20] The following table represents the δ‰ values of the testosterone metabolites (androsterone, etiocholanolone, 5α-Androstanediol[21] and 5β-Androstanediol[22]):

[Footnote continued from previous page]

Isotope Ratio Mass Spectrometry After Oral Administration of Testosterone, 28 Journal of Analytical Toxicology (Sept. 2004).

IRMS allows measurements of slight differences in the carbon isotope ratio ($^{13}C/^{12}C$) of the exogenous and endogenous testosterone. Synthetic testosterone is produced from precursors derived from plants with low ^{13}C content, whereas the ^{13}C and ^{12}C content in the natural endogenous form depends on the isotopic carbon composition of the food diet and is influenced by additional effects of human biological processing.

[20] Rather curiously, this is the same day that LNDD performed the first "A" T/E confirmation test.

[21] Also referred to as 5α-Adiol.

[22] Also referred to as 5β-Adiol.

	δ‰ Value
Androsterone	-25.05‰
Etiocholanolone	-23.63‰
5α-Androstanediol	-27.72‰
5βAndrostanediol	-23.73‰

The table below represents the δ‰ values of the ERC's (5β-Pregnanediol[23] and 11-Ketoetiocholanolone[24]):

	δ‰ Value
11-Ketoetio	-21.06‰
5β-Pdiol	-21.58‰

As described above, LNDD subtracts the ERC δ‰ value from the metabolite value. The table below represents the subtraction values.

	δ‰ Value
Etiocholanolone – 11-Ketoetio	-2.58‰
Androsterone – 11-Ketoetio	-3.99‰
5β-Adiol - 5β-Pdiol	-2.15‰

23 Also referred to as 5β-Pdiol.

24 Also referred to as 11-Ketoetio.

5α-Adiol - 5β-Pdiol	-6.14‰

c. The "B" Results: A Summary

On August 3, 2006, LNDD commenced the IRMS test on the "B" sample. The table below represents the δ‰ values of the testosterone metabolites (Androsterone, Etiocholanolone, 5α-Androstanediol and 5β-Androstanediol):

	δ‰ Value
Androsterone	-25.29‰
Etiocholanolone	-23.80‰
5α-Androstanediol	-27.43‰
5β-Androstanediol	-23.69‰

The table below represents the δ‰ values of the ERC's (5β-Pregnanediol and 11-Ketoetiocholanolone:

	δ‰ Value
11Ketoetio	-21.78‰
5βPdiol	-21.05‰

As described above, LNDD subtracts the ERC δ‰ value from the metabolite value. The table below represents the subtraction values.

	δ‰ Value
Etiocholanolone – 11Ketoetio	-2.02‰
Androsterone – 11-Ketoetio	-3.51‰
5β-Adiol - 5β-Pdiol	-2.65‰
5α-Adiol - 5β-Pdiol	-6.39‰

d. LABORATORY VALIDATION DOES NOT EQUAL "BECAUSE WADA SAID SO"

LNDD's positivity criteria is critical to this case. In simple terms, LNDD has declared Mr. Landis' IRMS analysis for Stage 17 adverse because of a single abnormal finding for one of testosterone's four metabolites -- 5α-Androstanediol. There is no evidence that LNDD ever validated its IRMS test method or positivity criteria. Instead, LNDD simply interpreted WADA TD2004EAAS as a harmonized document applicable to all WADA-accredited laboratories. It appears that LNDD simply transferred the "WADA Positivity Criteria" to its own laboratory without carrying out its own validation of that "criteria." This lack of validation by LNDD violates the minimum requirements applicable to a WADA-accredited laboratory.

If the "WADA Positivity Criteria" were a uniform approach mandated to be followed by all WADA-accredited laboratories, then one would assume that the criteria at all such laboratories would be identical. They are not.

USADA and LNDD apparently contend that it is sufficient that any one of the tested metabolites is sufficient to establish an AAF. If LNDD's and USADA's interpretation of the "WADA Positivity Criteria" were so clear, as USADA implies in its brief, then that "criteria would be uniformly applied in the manner interpreted by USADA and LNDD. It is not. For example, in 2006, the WADA-accredited laboratory in Lausanne stated as follows:

> According to the technical document of the WADA Laboratory Committee, an athlete would be reported as consistent with the administration of a steroid when the $^{13}C/^{12}C$-value measured for the **metabolites** differs significantly, i.e. by 3.0‰ or more from that of the urinary reference steroid chosen. (Baume et al., Use of Isotope Ratio Mass Spectrometry to Detect Doping with Oral Testosterone Undecoanate: Inter-Individual Variability of $^{13}C/^{12}C$ Ratio, Steroids 2006, at 6).

Consistent with this interpretation, the UCLA Olympic Laboratory applies an "all-metabolite" criteria. Its applicable SOP states:

> A positive report means that the delta values for both M1 and M2 are at least three standard deviations (SD) units less than the mean (average) of a group of 73 normal males, and the delta value for Pdiol is within 3SD of the mean of normal males. In addition . . . the two differences are more than 3 SD from the range of normal values. These criteria . . . **all must be met** for the sample to be declared positive."

See Exhibit GDC0451-0452 (emphasis added).

This comes as no surprise. WADA-accredited laboratories are autonomous and do not commonly share information concerning their anti-doping testing methods. However, it is clear – despite USADA's unsubstantiated representations to the contrary – that

different laboratories have adopted differing positivity criteria for the GC-C-IRMS test.[25] The critical effect of this lack of uniformity is that the same sample – tested using the same GC-C-IRMS machinery and software – can be considered both positive and negative for synthetic testosterone depending on which laboratory's method is used.

One major inconsistency among the laboratories is that each measures different metabolites and ERCs. The LNDD measures four metabolites: Androsterone, Etiocholanolone, 5α-Androstanediol, 5β-Androstanediol, and, two ERCs: 11-Ketoetiocholanolone and 5β-Pregnanediol. Cologne, on the other hand, measures two metablolites, Androsterone and Etiocholanolone, and one ERC, 5β-Pregnanediol. *See* Exhibit GDC0402-0403. Similar to Cologne, Australia measures two metabolites, Androsterone and Etiocholanolone, but in contrast, the only ERC measured is 11-Ketoetiocholanolone. Contrary to the above three laboratories, UCLA measures either two metabolites, Androsterone and Etiocholanolone, and no ERC, or it measures two different metabolites, 5α-Androstanediol and 5β-Androstanediol, and one ERC, Pdiol.[26]

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[25] Despite attempting to gain information from WADA-accredited laboratory known to be used GC-C-IRMS, Respondent was able to gain information concerning three other laboratories, in addition to LNDD, concerning their testing methods and positivity criteria.

[26] UCLA performs an initial analysis to determine the concentration the sample. If the sample is not sufficiently concentrated, UCLA measures only the Androsterone and Etiocholanolone values. If the sample is sufficiently concentrated, UCLA measures the 5α-Androstanediol and 5β-Androstanediol values and the 5β-Pregnanediol value. UCLA does not measure all five values for any given sample.

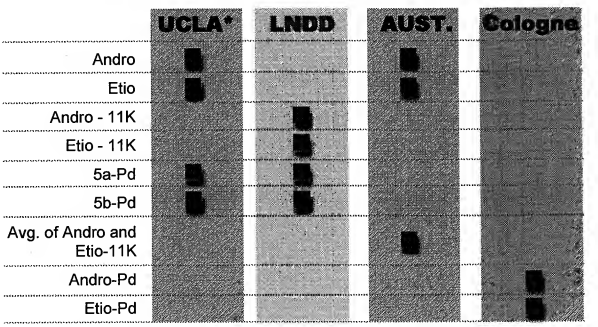
The table below sets forth the different metabolites and ERCs tested by the various laboratories.

Laboratory	Metabolite	ERC
LNDD	Androsterone, Etiocholanolone, 5α-Androstanediol, 5β-Androstanediol	11-Ketoetiocholanolone and 5β-Pregnanediol
Cologne	Androsterone and Etiocholanolone	5β-Pregnanediol
Australia	Androsterone and Etiocholanolone	11-Ketoetiocholanolone
UCLA Assay 1	Androsterone and Etiocholanolone	None
UCLA Assay 2	5α-Androstanediol and 5β-Androstanediol	5β-Pregnanediol

Another major inconsistency is the application of the individual measurements in determining the positivity of the sample. LNDD does not consider the absolute values of the metabolites tested; instead it subtracts the ERC values from the metabolite values. Specifically, LNDD subtracts the 5β-Pregnanediol value from the 5α-Androstanediol and 5β-Androstanediol values and subtracts the 11-Ketoetiocholanolone value from the Androsterone and Etiocholanolone values. Cologne does not consider the absolute metabolites values either, it considers the subtraction value from subtracting the 5β-Pregnanediol value from the Androsterone and Etiocholanolone values. Exhibit GDC0402-0403. In contrast, UCLA either considers the absolute values for

Androsterone or Etiocholanolone, or it considers only the subtraction value from subtracting the 5β-Pregnanediol value from 5α-Androstanediol and 5β-Androstanediol values. Exhibit GDC0451-0452 Contrary to the above three laboratories, Australia considers the absolute values for Androsterone and Etiocholanolone, and also considers the average of the Androsterone and Etiocholanolone minus the 11-Ketoetiocholanolone. The table below sets forth the data points considered by each laboratory.

Differences With Each Lab Doing IRMS Testing

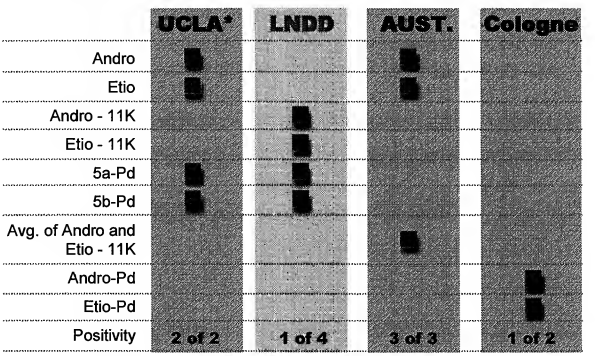


* Does either the Andro/Etio assay or the Diol assay

The last, and most important, inconsistency among the laboratories is the number of measurements that must surpass the threshold value to classify the sample as positive for synthetic testosterone. LNDD has four values it considers and only requires one of these values to surpass the threshold mark. Cologne considers two values and requires that at least one of these values surpass the threshold mark. Exhibit GDC0402-0403. Conversely, UCLA considers two values and requires that both values surpass the

threshold mark to be classified as positive. Exhibit GDC0451-0452. Similarly, Australia considers three values and requires that all three values surpass the threshold mark. The table below summarizes these differences.

Differences With Each Lab Doing IRMS Testing

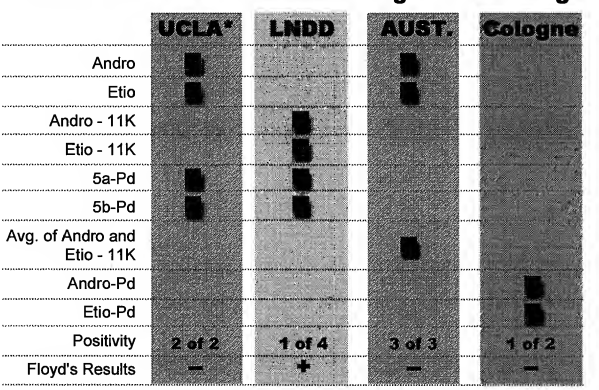


* Does either the Andro/Etio assay or the Diol assay

Considering the above positivity criteria for the UCLA, Australia and Cologne laboratories, Mr. Landis' sample would not be considered positive for synthetic testosterone. Using UCLA's positivity criteria, Mr. Landis' sample is negative because his Etiocholanolone and Androsterone values do not exceed the threshold value and both his 5α-Androstanediol – 5β-Pregnanediol and 5β-Androstanediol – 5β-Pregnanediol values do not exceed the threshold values. Mr. Landis' sample is negative applying the Cologne positivity criteria because neither Mr. Landis' Androsterone – 5β-Pregnanediol nor Etiocholanolone – 5β-Pregnanediol values exceed the threshold value. Additionally,

Mr. Landis' sample is negative applying the Australian positivity criteria because the Mr. Landis' Androsterone and Etiocholanolone values do not exceed the threshold value and the average of his Androsterone and Etiocholanolone values minus his 11-Ketoetiocholanolone values does not exceed the threshold value. Accordingly, applying the positivity criteria for three other WADA-Accredited laboratories using GC-C-IRMS, Mr. Landis' sample must be considered negative. The table below summarizes these findings.

Differences With Each Lab Doing IRMS Testing



* Does either the Andro/Etio assay or the Diol assay

Therefore, there are meaningful inconsistencies concerning the GC-C-IRMS testing methods and positivity criteria for different WADA-Accredited laboratories. This lack of uniformity belies any assertion that, as applied, the GC-C-IRMS test provides conclusive evidence of use of synthetic testosterone. This lack of uniformity belies any assertion that LNDD could or should simply transfer the "WADA Positivity Criteria" to

its laboratory without conducting its own validation. As demonstrated above, based on the same GC-C-IRMS data, three of the four laboratories would not declare Mr. Landis' sample positive for synthetic testosterone.

e. Lab Procedure Errors . . . Does It Ever End?

(i) LNDD USES OUTDATED IRMS SOFTWARE

It is axiomatic that the quality of LNDD's GC-IRMS analysis depends upon the quality of LNDD's IRMS instrument and corresponding software, and the competency of the operators. This principle is codified in the relevant international laboratory standards. International Standard ISO/EC 17025.5.5.11 (2005), *see* Exhibit GDC0311 requires that "where calibrations give rise to a set of correction factors, the laboratory shall have procedures to ensure that copies (e.g., in computer software) are correctly updated." Furthermore, ISO/EC 17025.5.4.7.2, Exhibit GDC0310 requires that "when computers or automated equipment are used in the acquisition, processing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that . . . (a) computer software developed by the user is documented in sufficient detail and is suitably validated as being adequate for use." *See id.*

LNDD describes its IRMS instrument as "an 'Isoprime' instrument purchased by LNDD from Micromass and installed at LNDD on 7 October 1998." Specifically, LNDD has a Generation A Isoprime, with the model number JA010, which means it is one of the first twenty Isoprimes made. LNDD states that the software used to control the Micromass Isoprime IRMS is the Optima GC 1.67-2 software ("OS2 Software"). The

Optima GC 1.67-2 software was originally written for the Micromass Optima IRMS and not the Isoprime IRMS instrument. *See* Exhibit GDC0514-0521 (Simon Davis Declaration). This software is now 10 years old and can be identified by its code number 1.67-2. Since version 1.67-2 of software was produced, there have been 6 major releases of software for the Isoprime. These include (1) Version 1.67-3 (OS2), (2) Version 1.67-4 (OS2), (3) Masslynx Version 3.5i (Windows NT), (4) Masslynx Version 3.6i (Windows NT), (5) Masslynx Version 4.0 (Windows XP) and (6) Ion Vantage Version 1.0 (Windows XP). The newer versions of the software have the following improvements:

A. The newer software included a new set of electronics with a new set of firmware for the systems head amplifier that corrected errors in the OS2 head amplifier firmware.

B. The newer software has the ability to control the GC portion of the GC-C-IRMS, whereas in the OS2 versions of the software, the operator has to manually program the GC.

C. The newer software traces any post-acquisition changes that are made to the data. For instance, if the software is re-processed with different integration parameters this would be recorded in all Masslynx and Ion vantage systems, but not in any OS2 systems.

D. The newer software contains a standards library for the automated storage and retrieval of standards values and data. OS2 requires the standards to be applied manually post acquisition.

E. The newer software has fully documented and tested background subtraction routines. The method and validity of the background routines in the OS2 software is unknown and undocumented. All documentation of the OS2 routines was lost when Micromass purchased Isotech (the developers of the original software).

F. The newer software has improved peak detection – the true nature of the OS2 detection methods is unknown as no documentation remains as to the method used.

G. The newer software provides "read-backs" that allow the true state of the Isoprime to be observed and recorded. The OS2 system offers no read backs.

H. The newer software works on a modern operating system for which you can obtain up-to-date anti-virus and malware software. OS2 Warp (the latest software that version 1.67-2 will run on) is no longer supported by IBM and no anti-virus or security software is available.

I. The newer software is compatible with a number of Laboratory Integrated Management Systems (LIMS). This is used for the control of results management.

Because of the age of the software, and the fact that it was not designed for this specific IRMS instrument, there is a serious question about its capability of delivering consistently accurate results. The new software would provide better peak detection, tested and documented background subtraction routines and would remove any errors in the head amplifier firmware. It would also provide a stable and modern operating system with up to date anti-virus and other security software.

USADA claims that the use of antiquated software had no impact on the results.[27] This claim is entirely speculative, given that the reprocessing of the electronic data files has not yet occurred. Respondent will supplement his brief on this issue after the reprocessing of the electronic data files has been completed.

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[27] Regardless of whether or not ISL requires software updates, the reprocessing will shed light on whether or not the reported results are accurate, which is ultimately the most important issue in the case.

(ii) THE LANDALUCE / SAME OPERATOR ERROR

Operator C. Mongongu was clearly involved in the A Sample testing. She also signed in with the B Sample testing, and is noted as having opened the B Sample. *See* Exhibits USADA0251, 0253. This issue will be further clarified during examination of the LNDD witnesses at the arbitration hearing.

(iii) HARDLY A FISHING EXPEDITION; THE SOPS FINALLY PROVE THAT MEASURE OF UNCERTAINTY DOES APPLY TO THE TEST RESULTS

The application of measurement of uncertainty in doping cases is equivalent to the measure of precision in a given result. Its importance is paramount in "forensic analytical chemistry (including doping analysis), where uncertainty has not only to be calculated with precision, but it also has to be both small and reliable enough to support effective decision making." *See* Exhibit GDC0453-0496 (Spirito, E. *et al.*, The Role of Measurement Uncertainty In Doping Analysis, Int. J. Risk Assessment and Management 5 (2/3/4), 378 (2005)). The determination and application of the measurement of uncertainty can have a determinative effect on the testing outcome. *Id.* ("It is not unusual for a result apparently exceeding the threshold, if taken as a single value or even as a mean value to not be correctly reported as 'above the threshold' if the measurement of uncertainty is not taken into account.").

LNDD has refused to explain how it arrived at its measurement of uncertainty for any of its testing processes, including GC-IRMS. In any case, LNDD consistently

ignores its own reported measurement of uncertainty. For example, [Androsterone – 11-Ketoetiocholanolone] was wrongly reported as abnormal in the "B" IRMS confirmation. *See* Exhibit USADA0352. Its value is not more negative than LNDD's reported minimum positivity criteria (-3.00‰) considering the stated measurement of uncertainty of +/- 0.8‰. The lab report itself notes that the measurement of uncertainty places the measured value between –2.71 and –4.31. Additionally, for both the "A" and "B" IRMS confirmations, the δ‰ values for Androsterone and 5α-Androstanediol are reported as outside the range for the normal population. In fact, however, if measurement of uncertainty is considered, all metabolites are inside the range for the normal population. *See* Exhibit USADA0186 and Exhibit USADA0352.

USADA claims at pages 54-56 of its Pre-Hearing Brief that (1) the LNDD positivity criteria for IRMS does not require that the δ‰ values be reduced by a factor or measurement uncertainty, and (2) that as a result, the LNDD positivity criteria for IRMS is a δ‰ of -3‰ without any consideration of measure of uncertainty. Respondent Landis reserves his right to supplement this Brief after full review and consideration of the additional SOP's requested some 6 months ago, that Mr. Landis just received from USADA. However, even a cursory review of those SOP's reveals that USADA is wrong.

Exhibit LNDD0618, which is a portion of the SOP applicable to declaring IRMS results, requires LNDD to report IRMS δ‰ values (difference between testosterone metabolite and ERC) as follows:

δ‰ value > -3.0‰ = negative / normal result

δ‰ values between -3.0‰ and -3.8‰ = unclassifiable

δ‰ values < -3.8‰ = positive / abnormal result

LNDD's own SOP, which Landis has been trying to obtain for over 6 months yet just received two days ago, proves that (1) LNDD **is** required to include the 0.8‰ measure of uncertainty in reporting its results, and (2) that LNDD **should not** have reported the Stage 17 values for Androsterone – 11-Ketoetiocholanolone as positive or abnormal[28].

(iv) LNDD'S GC-IRMS INSTRUMENT WAS IMPROPERLY USED AND MAINTAINED

In its discovery responses, LNDD claims its GC-IRMS instrument was working properly. Further, LNDD claims that: ". . . instrument performance in connection with the analysis of Sample #995474 was verified before the analyses were conducted, for example by tuning and calibrating the instrument, checking for the absence of leaks . . . ." LNDD, however, admits that it had no GC-IRMS operating manual. "The IRMS instrument manufacture provided to LNDD a working manual corresponding to Isochrom instead of Isoprime. LNDD has no manually specifically for Isoprime."

If LNDD had requested the Isoprime User Manual, it would have known of the following instruction:

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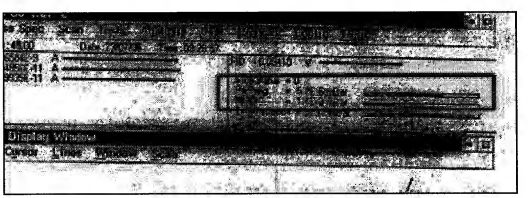
[28] The fact that LNDD's form for reporting IRMS results misstates its own positivity criteria as being a -3.0‰ difference instead of a -3.8‰ difference is itself a violation of ISL

Wait until the pressure shown on the Penning gauge falls below 5E-6 mbar. If there are no major leaks along the inlet capillaries the pressure will fall quickly and settle to the operating pressure between 2 and 4E-6 mbar. Failure to reach the operating pressure indicated major leaks. These must be cured before proceeding any further.

Caution: Ensure that the Penning gauge reading is less than 5E-6 mbar.

See Exhibit GDC0522.

LNDD, however, when it conducted Mr. Landis' sample, ran its GC-IRMS instrument in excess of the maximum allowable pressure, 5.2×10^{-6} millibars. *See* Exhibit USADA0176.



Id. Indeed, the Isoprime User Manual specifies that the operating Penning pressure should be between 2 and 4×10^{-6} millibars. Operating the GC-IRMS instrument at pressures of 5E-6 millibars or above can result in reduced sensitivity and precision of the reported results and increased variance values.

All mass spectrometers require a vacuum in order to operate properly, which involves ensuring that the ion beam can pass from the source to the detector system in a manner consistent with the manufacturer's specifications. Failure to operate this machine properly can result in (1) false detection of atmosphere gas as analyte gas and (2)

competitive ionization that results in the reduction of the sensitivity of the instrument to analyte gas, among others problems. Further, the increased pressure recorded in the Penning gauge possibly resulted from increased helium pressure in the system, causing similar defects in results. Lastly, the increased pressure will result in a decreased lifespan of the source filament, which also may increase the reported measure of variance. *See* Exhibit GDC0514-0521.

USADA claims that LNDD's failure to maintain the equipment or properly use it had no impact on the results (a claim that is patently absurd on its face). This claim is entirely speculative, given that the reprocessing of the electronic data files has not yet occurred. Respondent will supplement his brief on this issue after the reprocessing of the electronic data files has been completed.

f. RESERVATION OF ADDITIONAL ISSUES

The remainder of the issues that Mr. Landis will address with respect to the IRMS analysis will be upon receipt and review of the data to which he is entitled. These additional issues include (1) problems with linearity, (2) problems with stability, (3) problems related to the adherence to laboratory procedures; (4) problems related to maintenance of the IRMS instrument and (5) problems related to the reliability of the data.

VI.

CONCLUSION

In light of the totality of the errors discussed above, LNDD did not perform the GC/MS and IRMS test in accordance with WADA standards and other well-established

laboratory procedures. Accordingly, LNDD's test results are not reliable and this panel should dismiss the alleged doping charge.

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Respectfully submitted,

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